

Safety Reports

OTC Aspirin

Introductory Statement

The source of these reports are primarily from the FDA's Adverse Event Reporting System (AERS) and/or the published medical literature. AERS is a spontaneous, voluntary surveillance system. Reports are voluntarily reported by health care professionals and consumers to either the FDA directly or to the manufacturer. The manufacturer is required to submit these reports to the Agency for products with an NDA.

GI bleeding related to OTC Aspirin

All Case Reports (187) Submitted on GI Bleeding reported in association with OTC Aspirin for the year 2001.

Individual Safety Report



3516137-5-00-01

Sanofi-Synthelabo Inc.

Domain Facsimile

Approved by FDA on 3/22/94

Mfr report # 2000USA00658

JF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 3

A. Patient information			
1. Patient identifier	2. Age at time of event: NI or Date of birth: NI	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight NI lbs or NI kgs
in confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (s.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (m/d/yyyy)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____			
3. Date of event (m/d/yyyy)	NI	4. Date of this report (m/d/yyyy)	05/22/2000
5. Describe event or problem			
<p>This case was first received by Aventis Pharmaceuticals regarding their product Lovenox (Manufacturer Case ID US01-24477). Since the report included Plavix (clopidogrel), it was forwarded to Sanofi-Synthelabo.</p> <p>A pharmacist reports that a male patient experienced petechiae in the face, left eye subconjunctival hemorrhage, and a gastrointestinal bleed. The patient received Enoxaparin (1 mg/kg, Q12H) for a total of 10 doses. Concomitant medications included aspirin and Plavix, both were considered to have contributed to the bleeding events. Enoxaparin, aspirin, and Plavix were held. The patient had an ophthalmology and GI consult. The patient recovered and *</p>			
6. Relevant tests/laboratory data, including dates			
NI			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>End-stage renal failure with dialysis. Concomitant disease(s): Not reported</p>			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 PLAVIX			
#2 LOVENOX			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from to (or best estimate))	
#1 NI		#1 NI to NI	
#2 1 mg/kg Q12HR		#2 NI to NI Duration: 5 days	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 Not reported		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 Not reported		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 NI		#1 NI	
#2 NI		#2 NI	
9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction	
#1 NI		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 NI		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
None reported			

G. All manufacturers			
1. Contact office - name/address (& mfg site for devices)		2. Phone number	
Sanofi-Synthelabo Inc. 90 Park Avenue New York, NY 10016		(212) 551-4000	
4. Date received by manufacturer (m/d/yyyy)		5. (A)NDA # 20-839	
05/10/2000		IND # _____	
6. If IND, protocol #		PLA # _____	
7. Type of report (check all that apply)		pre-1938 yes	
5-day 15-day		OTC product yes	
10-day <input checked="" type="checkbox"/> periodic		8. Adverse event term(s)	
<input checked="" type="checkbox"/> Initial follow-up #		GI HAEMORRHAGE, PURPURA, CONJUNCTIVAL HAEMORRHAGE	
9. Mfr. report number			
2000USA00658			

E. Initial reporter			
1. Name, address & phone #			
Ms. _____ Hospital _____ Street _____ UNITED STATES *			
2. Health professional?	3. Occupation	4. Initial report sent to FDA	
<input checked="" type="checkbox"/> yes no	PHARMACIST	yes no unk	



Domain Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event. Item completed on continuation pages.

JUN 16 2000

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Individual Safety Report



3516137-5-00-02

Sanofi-Synthelabo Inc.

Domain Facsimile

Approved by FDA on 3/22/84

Mfr report #
2000USA00658

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 3

A. Patient information

1. Patient identifier _____ 2. Age at time of event: _____ or _____ Date of birth: _____ 3. Sex female male 4. Weight _____ lbs or _____ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

death _____ (mo/day/yr) life-threatening hospitalization - initial or prolonged

disability congenital anomaly required intervention to prevent permanent impairment/damage other: _____

3. Date of event (mo/day/yr) _____ 4. Date of this report (mo/day/yr) _____

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#3 **Aspirin**

#4 _____

2. Dose, frequency & route used

#3 **NI**

#4 _____

3. Therapy dates (if unknown, give duration) (month for best estimate)

#3 **NI to NI**

#4 _____

4. Diagnosis for use (indication)

#3 **Not reported**

#4 _____

5. Event abated after use stopped or dose reduced

#3 yes no doesn't apply

#4 yes no doesn't apply

6. Lot # (if known) #3 **NI** #4 _____

7. Exp. date (if known) #3 **NI** #4 _____

8. Event reappeared after reintroduction

#3 yes no doesn't apply

#4 yes no doesn't apply

9. NDC # - for product problems only (if known)

#3 **NI** #4 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mixing site for devices)

2. Phone number

3. Report source (check all that apply)

foreign study literature consumer health professional user facility company representative distributor other:

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 yes no OTC product yes no

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day 10-day periodic Initial follow-up #

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name, address & phone #

2. Health professional? yes no

3. Occupation

4. Initial reporter also sent report to FDA yes no unk

JUN 16 2000

FDA

Domain Facsimile of FDA Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event. Item completed on continuation pages.

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Individual Safety Report



3516137-5-00-03

Sanofi-Synthelabo Inc.

MDD WATCH	A.1. Patient Identifier	G.9. Mfr. report number 2000USA00658	Page 3 of 3
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B.5. Describe event or problem

[continuation:] enoxaparin was not rechallenged. His past medical history is significant for end-stage renal failure, for which he is receiving dialysis.

Corrective treatment: not reported

E.1. Name, address & phone #

[continuation:] Phone: [REDACTED]

JUN 16 2000

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VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved OMB No 3510-0291 Expires 12/31/00
See OMB statement on reverse

FDA Use Only
Triage unit
sequence # **134888**
CDER

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient identifier: [redacted] 2. Age at time of event: 90 Years or Date of birth: [redacted] 3. Sex: female male 4. Weight: 58 lbs or 58 kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death disability
 life-threatening congenital anomaly
 hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: 12/20/2000 4. Date of this report: 12/29/2000

5. Describe event or problem:
 3 antral ulcers found on EGD. Patient with 1 week history of black tarry stools, epigastric pain, weakness, vertigo, diarrhea. Biopsy for H. Pylori positive. On Ecotrin 1/day and Celebrex 200 mg bid prior to event for CAD/arthritis respectively. No PPI or H2 blocker.

6. Relevant tests/laboratory data, including dates see above. H/H 8.7/26.4

7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 PMH: Hypertension, arthritis.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 Ecotrin / 325 mg /
 #2 Celebrex / 200 mg /

2. Dose/Frequency/Route used
 #1 325 mg / QD / Oral
 #2 200mg / BID / Oral

3. Therapy dates (if unknown, give duration) From To (or best estimate)
 #1 01/01/2000 - 12/27/2000
 #2 01/01/2000 - 12/27/2000

4. Diagnosis for use (separate indications with commas)
 #1 Coronary artery disease
 #2 arthritis

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)
 #1 #1
 #2 #2

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only):
 - -

10. Concomitant medical products and therapy dates (exclude treatment of event)
 Lasix 20 mg QD, Klor Con 10 meQ qd

D. Suspect medical device

1. Brand name
 2. Type of device
 3. Manufacturer name & address
 4. Operator of device
 health professional
 lay user/patient
 other

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 JAN 2 2001

5. Expiration date
 6. model # MEDWATCH CTU
 catalog #
 serial #
 lot #
 other #

7. If implanted, give date
 8. If explanted, give date

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on _____

10. Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

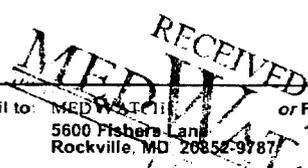
1. Name [redacted] phone # [redacted]
 [redacted] Hospital Pharmacy, [redacted] Blvd.
 [redacted] United States [redacted]

2. Health professional? yes no 3. Occupation Pharmacist 4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178



FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV134888

Individual Safety Report



For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved OMB No. 0910-0291 Expires 11/30/03
 FDA Use Only
 Triage unit sequence # **134950**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight [redacted] lbs or [redacted] kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year) 11/3/01

4. Date of this report (month/year) 11/3/01

5. Describe event or problem

11/01 PT- ADMITTED WITH CRUSHING CP

12/01 TAKEN TO CAT+ LAB FOR STENTING PROCEDURE

1/3/01 FOUND WITH BR/P/R DIAPHOREBSIS + HYPOTENSION

CXK Revealed
 Hgb drop of 3g (14.6 - 11.9)
 Hct drop 43.4 - 35.4

Planned endoscopic procedure to evaluate GI bleed

6. Relevant tests/laboratory data, including dates

pmH - Prostate CA - Radiation

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

#1 Integrelin

#2 ASA / Plavix

2. Dose, frequency & route used

#1 180mcg/kg bolus 2mg/kg/min

#2 325mg / 75mg qd

3. Therapy dates (if unknown, give duration)

#1 _____

#2 _____

4. Diagnosis for use (indication)

#1 CAD / Stenting procedure

#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name NA

2. Type of device _____

3. Manufacturer name & address _____

4. Operator of device

health professional

lay user/patient

other _____

5. Expiration date (month/year) _____

6. model # _____

7. If implanted, give date (month/year) _____

8. If explanted, give date (month/year) _____

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address _____ phone # _____

2. Health professional? yes no

3. Occupation _____

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH, 5600 Blaine Ave., Rockville, MD 20851-0787
 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a

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JAN 04 2001
 MEDWATCH CTU

RECEIVED

CTU134950

10/1

JAN-03-01 MED 17:02

Individual Safety Report



3641940-0-00-01

Triage unit sequence #

135029

Chen

A. Patient Information

1. Patient Identifier | 2. DOB: [redacted] | 3. Sex | 4. Weight
AGE: 65 yrs | MALE | 108.6 kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem
2. Outcomes attributed to adverse event:
[] death: [] disability
[X] life-threatening [] congenital anomaly
[X] Hospitalization [X] required intervention to
initial or prolonged prevent impairment/damage
[] other

3. Date of event 08/18/00 | 4. Date of this report 11/10/00

5. Describe event or problem
GI Bleed

6. Relevant test/laboratory data, including dates
PLEASE SEE ATTACHED

7. Other relevant History, including preexisting medical
conditions
[redacted] is a 65 year old black male with a history of recently
diagnosed bladder cancer, hypertension, status post
cerebrovascular accident, who presents with bright red
blood per rectum. Patient was at the time receiving
PLEASE SEE ATTACHED

C. Suspect Medication(s)

1. Name
#1 : ASPIRIN
#2 : DICLOFENAC 75MG/MISOPROSTOL 2C
2. Dose, frequency & route used | 3. Therapy dates
#1: #1 :
#2: #2 :
4. Diagnosis for use(indication) | 5. Event abated after use
stopped or dose reduced?
#1: #1: [N/A]
#2: #2: [N/A]
6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after
reintroduction
#1: #1: #1: []
#2: #2: #2: []
9. (Not applicable to adverse drug event reports)
10. Concomitant medical products/therapy dates(exclude treatment)
BACTRIM DS EQUIVALENT TAB
PHENYTOIN 100 MG CAP
POSINOPRIL NA 20MG TAB
PLEASE SEE ATTACHED

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event
involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: PHARMACY SERVICE
[redacted]

2. Health professional? | 3. Occupation | 4. Reported to Mfr.
[YES] | [PHARMACY RESID] | [NO]

5. If you don't want your identity disclosed to the Manufacturer,
place an "X" in the box. [X]

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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JAN 04 2001

MEDWATCH CTU

DOB

JAN 05 2001

CTU135029

Individual Safety Report



3641940-0-00-02

Triage unit sequence # 135029

A. Patient Information

1. Patient Identifier | 2. DOB: | 3. Sex | 4. Weight
AGE: yrs | kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem
2. Outcomes attributed to adverse event
[] death [] disability
[] life-threatening [] congenital anomaly
[] Hospitalization [] required intervention to prevent impairment/damage
initial or prolonged [] other

3. Date of event 08/18/00 4. Date of this report 11/10/00

5. Describe event or problem

6. Relevant test/laboratory data, including dates

7. Other relevant History, including preexisting medical conditions

Mail to: MedWatch 5600 Fishers Lane Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500

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C. Suspect Medication(s)

1. Name #3: IBUPROFEN GEL 5% 100 ML

2. Dose, frequency & route used #3: 3. Therapy dates #3:

4. Diagnosis for use(indication) #3: 5. Event abated after use stopped or dose reduced? #3: [N/A]

6. Lot # (if known) #3: 7. Exp. date #3: 8. Event reappeared after reintroduction #3: []

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates(exclude treatment)

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #:

2. Health professional? 3. Occupation 4. Reported to Mfr.

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. []

DSS

JAN 05 2003

135029

Individual Safety Report



3641940-0-00-03

135029

ATTACHMENT PAGE

PATIENT ID: [REDACTED]

SUSPECT MEDICATION: ASPIRIN

DATE OF EVENT: 8/18/00

Section B. Part 6. Relevant Test/Laboratory Data Continued:

TEST: HGB RESULTS: L 8.4 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/25/00@17:41
 TEST: HCT RESULTS: L 25.3 % H:48.2/L:40.2 COLLECTION DATE: 8/25/00@17:41
 TEST: HGB RESULTS: L 9.7 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/23/00@19:32
 TEST: HCT RESULTS: L 29.5 % H:48.2/L:40.2 COLLECTION DATE: 8/23/00@19:32
 TEST: HGB RESULTS: L 10.3 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/23/00@00:01
 TEST: HCT RESULTS: L 30.6 % H:48.2/L:40.2 COLLECTION DATE: 8/23/00@00:01
 TEST: HGB RESULTS: L 7.9 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/22/00@05:03
 TEST: HCT RESULTS: L 23.7 % H:48.2/L:40.2 COLLECTION DATE: 8/22/00@05:03
 TEST: HGB RESULTS: L 8.7 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/21/00@13:50
 TEST: HCT RESULTS: L 26.1 % H:48.2/L:40.2 COLLECTION DATE: 8/21/00@13:50
 TEST: HGB RESULTS: L 12.0 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/19/00@03:40
 TEST: HCT RESULTS: L 36.3 % H:48.2/L:40.2 COLLECTION DATE: 8/19/00@03:40
 TEST: HGB RESULTS: L 8.5 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/27/00@07:00
 TEST: HCT RESULTS: L 25.8 % H:48.2/L:40.2 COLLECTION DATE: 8/27/00@07:00
 TEST: HGB RESULTS: L 8.1 g/dL H:17.2/L:12.8 COLLECTION DATE: 8/26/00@22:02
 TEST: HCT RESULTS: L 24.5 % H:48.2/L:40.2 COLLECTION DATE: 8/26/00@22:02

Section B. Part 7. Other Relevant History Continued

aspirin 81MG for prevention of stroke. He was also ordered arthrotec BID and topical ibuprofen. His vital signs were stable and a gastric lavage was negative. He lost an estimated 500 to 1,000 cc of blood. He continued to have small episodes of bright red blood per rectum and received a platelet transfusion in the MICU an upper endoscopy was performed which was also negative. A colonoscopy was attempted but was not helpful because of large amounts of blood clots; the procedure had to be aborted early because of a vasovagal response with hypotension. On August 22 the hematocrit dropped again significantly. He received 2 units of packed red blood cells. On August 22 a repeat colonoscopy was performed which demonstrated a single sigmoid diverticuli without active bleeding. The patient had an additional bleed on August 23 and at this point his hematocrit dropped from 29 to 26. Once the patient's hematocrit was stable without any evidence of rebleed for 48 hours he was retransferred back to the Medical Team. On Aug 31, the patient went AWOL without any medications. Follow-up on 11/9/00 shows that he is receiving aspirin 81mg QD as an outpatient. His arthrotec has been discontinued. He remains on ibuprofen gel.

Section C. Part 10. Concomitant Drugs Continued

HYDROCHLOROTHIAZIDE 25 MG TAB
 FELCLODIPINE 10 MG TAB
 ANALGESIC BALM CINT 30 GM
 OCEAN NASAL SPRAY
 PIRBUTEROL AUTOHALER 400 DOSE
 IPRATROPIUM/ALBUTERCL INHALER

DSS

JAN 05 2001

135029

Individual Safety Report



OLUNTARY reporting
 thprofessionalsof adverse
 itsand product problems

Form Approved: OMB No. 0910-0201 Expires: 11/30/00
 See OMB Statement on Reverse

FDA Use Only

Triage unit sequence# **135068**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of ...

CDER

A. Patient information

1 Patient identifier: [redacted] 2 Age at time of event: 54 3 Sex: male 4 Weight: 155 lbs

B. Adverse event or product problem

1 Adverse event and/or Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply):
 death disability
 life-threatening congenital anomaly
 hospitalization or initial or prolonged required intervention to prevent permanent impairment/damage
 other

3 Date of event: Aug 20, 2000 4 Date of this report: Dec 28, 2000

5 Describe event or problem:
 -- On Aug 20 had dark stool in morning.
 -- In afternoon, felt weak and faint, and short of breath. Heart beating at fast rate.
 -- Taken to hospital in ambulance.
 -- Emergency doctor did rectal check and found evidence of internal bleeding.
 -- Diagnosed upper gastro-intestinal bleeding. Admitted to hospital.
 -- On Aug 22, an endoscopy showed a duodenal ulcer, which had stopped bleeding.
 -- Hospital blood tests showed that I had lost 30 percent of my red blood cell value. Suffering from anemia.
 -- Stayed in hospital until Aug 24.
 -- Recovered at home over two months, taking Prev Acid to heal ulcer, plus iron and vitamins and foods to build up red blood cells.

6 Relevant tests/laboratory data, including dates:
 -- Aug 20: hospital blood tests
 -- Aug 22: endoscopy at hospital

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 I had been taking low-strength aspirin for three years, prescribed for heart murmur. Likely that the aspirin made an ulcer, and that the Celebrex made the ulcer bleed.
 Now and then, one to three times a month, I had also been taking Advil, 200 MG, for headaches. One pill only, each time.

C. Suspect medication(s)

1 Name (give label strength & manufacturer, if known):
 #1 Aspirin, low-strength, coated pill (Bayer)
 #2 Celebrex, 200 MG Capsule

2 Dose, frequency & route used:
 #1 one pill, daily
 #2 200 MG, Twice, Daily

3 Therapy dates (if unknown, give duration):
 #1 3 years
 #2 Aug 1-11, 2000

4 Diagnosis for use (indication):
 #1
 #2

5 Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6 Lot# (if known): #1 #2 7 Exp. date (if known): #1 #2

8 Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9 NDC# (for product problems only):
 #1 #2

10 Concomitant medical products and therapy dates (exclude treatment of event):

D. Suspect medical device

1 Brand name:
 2 Type of device:
 3 Manufacturer name & address:
 4 Operator of device:
 health professional
 lay user/patient
 other

5 Expiration date (month/year):
 6 Model #:
 7 If implanted, give date (month/year):
 8 If explanted, give date (month/year):

9 Device available for reevaluation? (Do not send to FDA)
 yes no returned to manufacturer on (month/year)

10 Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

1 Name & address: Mr. [redacted] St. [redacted] DSS
 2 Health professional? yes no
 3 Occupation: writer/photographer
 4 Also reported to:
 manufacturer
 user/facility
 distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

PLEASE TYPE OR USE BUBBLES

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 JAN 05 2001
 MEDWATCH CTU



Mailto: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787
 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CT4 135068



3641984-9-00-02

135068

Mr. [REDACTED] St.
[REDACTED]
[REDACTED]

Tel: [REDACTED]

December 28, 2000

MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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MEDWATCH CTU

Dear MedWatch:

Please find enclosed a voluntary report of a life-threatening bleeding ulcer and hospitalization experience as a result of taking two prescribed drugs, Aspirin and Celebrex.

Another prescribed drug, Advil, may also have played a role.

As my report notes:

I had been taking low-strength, coated aspirin (Bayer) for about three years. A dose of one pill daily, prescribed for a heart murmur.

(I had also been taking Advil, now and then for headaches. One 200 MG pill a day, one to three times a month. The night before the gastro-intestinal bleeding, I took one Advil pill for a headache.)

In late July, 2000, a doctor prescribed Celebrex for tendonitis in my wrists and forearms. The prescription was: 200 MG capsule, twice daily, for 14 days. I took this drug as prescribed for 10 days in August.

Then, on August 20, about seven days after I stopped taking the Celebrex, I had a dark stool in the morning. In the afternoon, I felt weak and short of breath, and started perspiring. An ambulance was called. The paramedic found that my heart rate was well above 90.

I was taken to the hospital by ambulance. The emergency doctor did a rectal check and found evidence of internal bleeding. The doctor, noting that I had had a dark stool, diagnosed upper gastro-intestinal bleeding. I was admitted to the hospital.

388
...2
JAN 05 2001

CTU 135068



3641984-9-00-03

135068

FDA Report

2

December 28, 2000

Blood tests in the hospital showed I was suffering from extreme anemia. I had lost about 30 percent of my red blood cells.

On August 22, I had an endoscopy at the hospital. It showed that I had a duodenal ulcer, which had stopped bleeding. The biopsy showed that it was a non-bacterial ulcer.

The gastroenterologist who did the endoscopy said that it was the Celebrex that made the bleeding ulcer. He said that he sees many similar cases.

(Another gastroenterologists, who I saw recently for a follow-up check on the duodenal ulcer, thinks the ulcer formed as a result of taking the low-strength aspirin, and that the Celebrex made the ulcer bleed.)

I was released from the hospital on August 24, with instructions to rest and take Prev Acid to heal the ulcer; along with iron pills, multiple vitamins and a diet including red meat to build up my blood count.

It took me a month to get back to a functioning energy level; and one more month to get back to my regular red blood cell count.

I am still continuing to have gastro-intestinal after effects, including acid reflux.

So, I went through a very stressful experience, and I lost over two months of my regular life. Plus I am experiencing unsettling after effects.

Considering all of this, I think that the FDA needs to issue instructions to the manufacturers of Aspirin and Celebrex (and the makers of similar drugs) to provide underscored notices on their product information to pharmacists, doctors and patients about the health hazards of taking Aspirin, and of taking Aspirin and Celebrex (or other anti-inflammatories) together.

At the moment, the information issued by pharmacists for Celebrex re drug interactions states: "Aspirin as prescribed by your doctor for reasons such as heart attack or stroke prevention (i.e. non-arthritis doses) should be continued."

In my case, after the Celebrex was prescribed by a neurologist, I consulted my family doctor about whether it was safe to take this anti-inflammatory drug. He said this drug should not cause any significant problems. Both the neurologist, and of course my

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JAN 05 2001

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MEDWATCH CTU

CTG 135068



135068

FDA Report

December 28, 2000

family doctor, were aware that I was taking one low-strength aspirin daily; and that I had been taking it this way for about three years.

Both doctors ought to have considered this more carefully, especially since the FDA has reported a much higher incidence of stomach and ulcer bleeding when Aspirin and Celebrex are taken at the same time. They also ought to have advised me not to take any anti-inflammatory pain relievers, such as Advil, for headaches. They could have suggested Tylenol, a non anti-inflammatory.

Therefore, I think it is highly important for the FDA to issue instructions to doctors about the dangers of combining even low-strength aspirin, and other anti-inflammatories such as Advil, with Celebrex and similar drugs.

The FDA also needs to make more tests on Celebrex and similar anti-inflammatories. I think these drugs were released into the market with incomplete testing, especially in relation to drug interaction hazards.

It is my understanding that the risk of stomach and ulcer bleeding from Celebrex, when combined with Aspirin, is seven to ten percent. This figure, seven to ten people out of one hundred suffering from gastro-intestinal bleeding, is in my view unacceptable.

I look forward to hearing what actions the FDA will be taking on the important matters of:

- The adverse effects of taking low-strength aspirin.
- The dangers of combining low-strength aspirin, and similar anti-inflammatory drugs, with Celebrex or related drugs.

Thank you for your attention.

Sincerely yours,

[Redacted signature]

c.c. U.S. Secretary of Health
interested doctors
interested citizens

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JAN 05 2001
MEDWATCH CTU

OSS
JAN 05 2001

CTG 135068

Individual Safety Report



Voluntary reporting
by health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/00
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

135177

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

COER

A. Patient information			
1. Patient identifier Unspecified In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:			
3. Date of event 10/22/2000	4. Date of this report 01/07/2001		
5. Describe event or problem GI bleed causing hospital admission			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)		
1. Name (Product Name) #1 aspirin #2 rofecoxib	(Labeled Strength) / 325mg / 25mg	(Mfr/Labeler) / / merck
2. Dose/Frequency/Route used #1 325mg /qd /Oral #2 25mg /qd /Oral	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 05/19/2000 - 10/19/2000 #2 08/19/2000 - 10/19/2000	
4. Diagnosis for use (separate indications with commas) #1 #2		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2	
9. NDC # (for product problems only) - -		
10. Concomitant medical products and therapy dates (exclude treatment of event)		

D. Suspect medical device	
1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
RECEIVED JAN 08 2001	
6. model #	5. Expiration date
catalog # MEDWATCH CTU	7. If implanted, give date
serial #	8. If explanted, give date
lot #	
other #	
9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)			
1. Name		phone #	
Drive			
United States			
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user/facility <input type="checkbox"/> distributor	
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-0782
or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event

CTU 135177

Individual Safety Report



3645465-8-00-01

or VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0281 Expires 11/01
See OMB statement for changes

FD-108 (Rev. 10/01)
Trace unit
sequence # 135287

Page 1 of 1

A. Patient information

1. Patient identifier: [redacted] 2. Age at time of event: 79 or Date of birth: [redacted] 3. Sex: male 4. Weight: 74.1 lbs or 33.6 kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (m/d/yyr)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event (m/d/yyr): 1/31/01 4. Date of this report (m/d/yyr): 1/31/01

5. Describes event or problem:
 1/10/01 PT. ADMITTED WITH CRUSHING CP
 1/21/01 TAKEN TO CATH LAB FOR STENTING PROCEDURE
 1/31/01 FOUND WITH BRBPR DIAPHORESIS + HYPOTENSION
 CX Review
 Hgb drop of 3g (14.6 - 11.4)
 Hct drop 43.4 - 35.4
 Planned endoscopic procedure to evaluate GI bleed.

6. Relevant tests/laboratory data, including dates:
 PMH - Prostate CA ± Radiation

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known):
 #1 Intralipid
 #2 ASA (3) Plavix

2. Dose, frequency & route used:
 #1 180mg/kg bolus 2mg/kg/min
 #2 325mg/d / 75mg qd

3. Therapy dates (if unknown, give duration, from to, or best estimate):

4. Diagnosis for use (indication):
 #1 CAD / Stenting procedure

5. Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known): #1 _____ #2 _____ 7. Exp date (if known): #1 _____ #2 _____

9. NDC # (for product problems only):

10. Concomitant medical products and therapy dates (exclude treatment of event):

D. Suspect medical device

1. Brand name: NA

2. Type of device:

3. Manufacturer name & address:
 RECEIVED
 JAN 10 2001
 MEDWATCH CTU

4. Operator of device:
 health professional
 lay user/patient
 other:

5. Expiration date (m/d/yyr):

6. model #: _____ catalog #: _____ serial #: _____ lot #: _____ other #: _____

7. If implanted, give date (m/d/yyr):

8. If explanted, give date (m/d/yyr):

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on _____ (m/d/yyr)

10. Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

1. Name & address: [redacted] phone #: [redacted]
 [redacted] RPH
 [redacted] RCAD

2. Health professional? yes no 3. Occupation: _____ 4. Also reported to:
 manufacturer
 user/patient
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

CTV135 287

FDA Mail to: MEDWATCH 5800 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178



3645934-0-00-01

PRINT DATE: 08-JAN-2001 11:42:38

Approved by FDA on September 17, 1993

MEDWATCH

SEARLE Drug Experience Report

U.S. REPORTING

Searle Research and Development

Mfr report #	001128-SK671
UFIDat report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient identifier	2. Age at time of event: 34 Yrs or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight UNK lbs or kg
-----------------------	---	---	----------------------------------

In confidence

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: Medically Significant

3. Date of event (m/d/yyyy)	NOV 16 2000	4. Date of this report (m/d/yyyy)	DEC 28 2000
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5. Describe event or problem

On Nov-22-00, a physician reported an adverse event on Celebrex to a Pfizer sales representative. An 84 year old female patient started Celebrex (celecoxib) 100 mg daily on an unknown date for an unknown indication. The patient was also taking aspirin 325 mg daily, for an unknown indication. On Nov-16-00, the patient experienced a gastrointestinal bleed and was, apparently, hospitalized. Celebrex was discontinued on Nov-16-00 in response to the event. It is unclear if the aspirin was discontinued but the physician did report that he suspected the aspirin over the Celebrex as possible cause of the gastrointestinal bleed.

Additional information has been requested.

6. Relevant test/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 CELEBREX	#1 Unknown - NOV 16 2000
#2 ASPIRIN	#2 UNKN CWN
2. Dose, frequency & route used	5. Event abated after use stopped or dose reduced
#1 100.000 MG QD PO	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 325.000 MG QD PO	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
4. Diagnosis for use (indication)	8. Event reappeared after reintroduction
#1 UNKN CAUSE MORB/MORT NEC	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 UNKN CAUSE MORB/MORT NEC	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 UNK	#1 UNK
#2 UNK	#2 UNK
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
UNKNOWN	

G. All manufacturers

1. Contact office - name/address	2. Phone number
Therese M. Kitt, M.D. G.D. Searle and Co. 9855 Woods Drive Skokie, Illinois 60077	(847) 581-7874
4. Date received by manufacturer (m/d/yyyy)	3. Report source (check all that apply)
NOV 22 2000	<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input checked="" type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
5. (A) NDA # 20-998	
IND # [REDACTED]	
PLA #	
pre-1938 <input type="checkbox"/> yes	
OTC product <input type="checkbox"/> yes	
6. If IND, protocol #	8. Adverse event term(s)
	GI HEMORRHAGE
7. Type of report (check all that apply)	
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # 0 (Rev No. 0)	
9. Mfr. report number	
001128-SK671	

E. Initial reporter

1. Name, address & phone #

[REDACTED] MD
[REDACTED] Avenue
[REDACTED]
UNITED STATES
Telephone Nr: [REDACTED]

JAN 10 2001

2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation MD	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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001128-SK671

CELEBREX



3648280-4-00-01

MEDWATCH

HE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Voluntary reporting
professionals of adverse
events and product problems

Page 1 of 1

COER

Form Approved OMB No. 0916-0291 Expires 12/31/04
See OMB statement on reports

FDA Use Only	H Pad
Triage unit sequence #	<u>135622</u>

A. Patient information

1. Patient identifier <u>1151</u>	2. Age at time of event: <u>80</u>	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight <u>82</u> lbs or <u>kg</u>
Date of birth: <u>[redacted]</u>			

B. Adverse event or product problem

Adverse event and/or Product problem (e.g., defects/malfunctions)

Outcomes attributed to adverse event (check all that apply):

- death
- life-threatening
- hospitalization - initial or prolonged
- disability
- congenital anomaly
- required intervention to prevent permanent impairment/damage
- other

Date of event (m/d/yyyy): 10/26/00

Date of this report (m/d/yyyy): 11/3/00

Describe event or problem

Pt presented to ER 10/26/00 c 2-day h/o BRBPR + ^{nose bleed} h/o dropped from baseline 11 to 9.6 Pt was transfused c 4U FFPR and ^{given vit k 10mg} admitted to MICU. EGD was performed as was colonoscopy

Blood + scattered diverticula were seen, but no source of bleed was uncovered

to X 7 days

OUTCOME
PATIENT WAS SWITCHED TO: ASA, clopidogrel, warfarin
were d/c'd.

NAME OF THE PHYSICIAN WHO PRESCRIBED THE DRUG: [redacted]

Relevant tests/laboratory data, including dates

<u>10/26/00</u>	<u>11/1/00</u>
H/H <u>8.4/22.6</u>	H/H <u>10.5/31.0</u>
Cr <u>1.6</u>	Cr <u>1.4</u>
<u>PT 16.8</u>	<u>PT 14.3</u>
<u>INR 3.1</u>	<u>INR 1.0</u>

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

Prostate ca Afib
laryngostomy CHF
hypothyroid GERD
COPD
hypocalcemia
CAD s/p stent 10/00

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

OR FAX TO:
1-800-FDA-0178

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 <u>ASA</u>	#1 <u>10/15 10/6 - 10/26</u>
#2 <u>clopidogrel</u>	#2 <u>10/15 10/6 - 10/26</u>
#3 <u>warfarin</u>	#3 <u>10/15 10/6 - 10/26</u>
2. Dose, frequency & route used	4. Diagnosis for use (indication)
#1 <u>325mg QD</u>	#1 <u>Afib, CAD</u>
#2 <u>75mg @ 3.5mg qd</u>	#2
6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2
9. NDC # (for product problems only)	8. Event abated after use stopped or dose reduced
	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
	8. Event reappeared after reintroduction
	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event)	
<u>Sg Levothyroxine 0.15mg QD amoxiclav 500mg TID</u>	
<u>Aib/lpr MDI MVI simvastatin 40mg QHS</u>	
<u>Atrovent MDI Doxyc 125g TID</u>	
<u>metoprolol 25mg BID Bicalutamide 50mg QD</u>	

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user patient

other

5. Expiration date (m/d/yyyy)

6. Model #

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

VAMed Ctr - Lakeside
333E. Huron St. (M/C 119)
Chicago, IL 60611

2. Health professional? yes no

3. Occupation PharmD Candidate

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box



Voluntary reporting by health professionals of adverse events and product problems

FDA

CDER

Form Approved: OMB No. 0910-0041. FDA Use Only. Triage unit sequence # 136002

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient identifier: 7489. 2. Age at time of event: 49. 3. Sex: male. 4. Weight: 190 lbs.

B. Adverse event or product problem

1. Adverse event and/or Product problem. 2. Outcomes attributed to adverse event: life-threatening, hospitalization - initial or prolonged.

3. Date of event: 12/6/00. 4. Date of this report: 12/15/00.

Describe event or problem: GI bleed Hgb 3.6

Relevant tests/laboratory data, including dates

Hgb 3.6 RECEIVED JAN 19 2001 MEDWATCH CTU

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

GI bleed - gastritis, duodenitis, ulcer depression schizophrenia HTN

Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

C. Suspect medication(s)

1. Name: Aspirin. 2. Dose, frequency & route used: 160mg po qd. 3. Therapy dates. 4. Diagnosis for use. 5. Event abated after use. 6. Lot #. 7. Exp. date. 8. Event reappeared after reintroduction. 9. NDC #. 10. Concomitant medical products and therapy dates: Bupropion, Risperidone, Captopril, Insulin.

D. Suspect medical device

1. Brand name. 2. Type of device. 3. Manufacturer name & address. 4. Operator of device. 5. Expiration date. 6. model #. 7. If implanted, give date. 8. If explanted, give date. 9. Device available for evaluation? 10. Concomitant medical products and therapy dates.

E. Reporter (see confidentiality section on back)

1. Name, address & phone #. 2. Health professional? 3. Occupation. 4. Also reported to. 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



3651283-7-00-01

MEDwatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Approved by FDA on 10/20/93

Triage unit sequence # 136009

COOL

Page 1 of 1

A. Patient Information

1. Patient Identifier [redacted] 2. DOB: [redacted] 3. Sex: MALE 4. Weight: 90.3 kg
AGE: 76 yrs

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem
2. Outcomes attributed to adverse event
[] death [] disability
[] life-threatening [] congenital anomaly
[X] Hospitalization [X] required intervention to prevent impairment/damage
initial or prolonged [] other

3. Date of event: 12/07/00 4. Date of this report: 12/13/00

5. Describe event or problem
GI BLEED

6. Relevant test/laboratory data, including dates
PLEASE SEE ATTACHED

7. Other relevant History, including preexisting medical conditions
ALSO ON ETODOLAC

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

C. Suspect Medication(s)

1. Name
#1: ASPIRIN

2. Dose, frequency & route used
#1: 325mg po qd
3. Therapy dates
#1:

4. Diagnosis for use (indication) #1:
5. Event abated after use stopped or dose reduced?
#1: [N/A]

6. Lot # (if known) #1:
7. Exp. date #1:
8. Event reappeared after reintroduction #1: []

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
ATENOLOL 50MG TAB
ASCORBIC ACID 500MG TAB
TERAZOSIN HCL 5MG CAP
PLEASE SEE ATTACHED

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #:
[redacted]
VA MEDICAL CENTER 135 E. 38TH STREET
ERIE, PENNSYLVANIA 16504-1596 814-868-8661

2. Health professional? [YES] 3. Occupation: PHARMACIST 4. Reported to Mfr. [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

RECEIVED

DSS

JAN 19 2001

JAN 22 2001

MEDWATCH CTU

CTU 136009



3651283-7-00-02

136009

ATTACHMENT PAGE

SUSPECT MEDICATION: ASPIRIN

DATE OF EVENT: 12/7/00

PATIENT ID: [REDACTED]

Section B. Part 6. Relevant Test/Laboratory Data Continued:

- TEST: HGB RESULTS: L 10.6 g/dl H:18/L:14 COLLECTION DATE: 12/11/00@10:30
- TEST: HCT RESULTS: L 31.1 % H:52/L:42 COLLECTION DATE: 12/11/00@10:30
- TEST: RBC RESULTS: L 2.9 mil/ul H:6.1/L:4.7 COLLECTION DATE: 12/10/00@06:30
- TEST: HGB RESULTS: L 9.6 g/dl H:18/L:14 COLLECTION DATE: 12/10/00@06:30
- TEST: RDW RESULTS: 13.1 % H:14.5/L:11.5 COLLECTION DATE: 12/10/00@06:30
- TEST: HGB RESULTS: L 10.0 g/dl H:18/L:14 COLLECTION DATE: 12/9/00@05:30
- TEST: HCT RESULTS: L 29.0 % H:52/L:42 COLLECTION DATE: 12/9/00@05:30
- TEST: PLT RESULTS: L 70 thou/ul H:400/L:130 COLLECTION DATE: 12/9/00@05:30
- TEST: HGB RESULTS: L 10.4 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@15:00
- TEST: HCT RESULTS: L 30.5 % H:52/L:42 COLLECTION DATE: 12/8/00@15:00
- TEST: PLT RESULTS: L 84 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@15:00
- TEST: HGB RESULTS: L 10.5 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@10:30
- TEST: HCT RESULTS: L 30.8 % H:52/L:42 COLLECTION DATE: 12/8/00@10:30
- TEST: MCV RESULTS: H 97.5 fl H:94/L:80 COLLECTION DATE: 12/8/00@10:30
- TEST: PLT RESULTS: L 87 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@10:30
- TEST: HGB RESULTS: L 10.8 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@05:30
- TEST: HCT RESULTS: L 31.2 % H:52/L:42 COLLECTION DATE: 12/8/00@05:30
- TEST: MCV RESULTS: H 97.5 fl H:94/L:80 COLLECTION DATE: 12/8/00@05:30
- TEST: PLT RESULTS: L 87 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@05:30
- TEST: INR RESULTS: 1.33 COLLECTION DATE: 12/7/00@16:14
- TEST: HGB RESULTS: L 11.4 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@16:14
- TEST: HCT RESULTS: L 33.2 % H:52/L:42 COLLECTION DATE: 12/7/00@16:14
- TEST: HGB RESULTS: L 12.0 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@15:00
- TEST: HCT RESULTS: L 35.0 % H:52/L:42 COLLECTION DATE: 12/7/00@15:00
- TEST: HGB RESULTS: L 13.5 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@09:28
- TEST: HCT RESULTS: L 38.6 % H:52/L:42 COLLECTION DATE: 12/7/00@09:28
- TEST: PLT RESULTS: L 114 thou/ul H:400/L:130 COLLECTION DATE: 12/7/00@09:28

Section C. Part 10. Concomitant Drugs Continued

- A & D OINT(60GM)
- MULTIVITAMIN CAP/TAB
- ASPIRIN 325MG EC TAB
- ACETAMINOPHEN 325MG TAB
- ETODOLAC 400MG TAB
- GENTAMICIN SULFATE 0.1% CREAM
- PHYTONADIONE INJ

12/07/00-12/07/00

DSS

JAN 2 2 2001

136009



Approved by FDA on 10/20/93

MEDWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 135962

Page 1 of 2 *AM 1 COB*

A. Patient Information

1. Patient Identifier [redacted] | 2. DOB: [redacted] | 3. Sex: MALE | 4. Weight: 90.3 kg
AGE: 76 yrs

B. Adverse Event or Product Problem

1. Adverse Event Product problem
2. Outcomes attributed to adverse event
 death disability
 life-threatening congenital anomaly
 Hospitalization required intervention to prevent impairment/damage
initial or prolonged other

3. Date of event: 12/11/00 | 4. Date of this report: 12/13/00

5. Describe event or problem
GI BLEED

6. Relevant test/laboratory data, including dates
PLEASE SEE ATTACHED

7. Other relevant History, including preexisting medical conditions

ALSO ON ASPIRIN

osteomyelitis, HTN, chronic renal insuffic, Nitroglycerin, PVD

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

C. Suspect Medication(s)

1. Name
#1: ASPIRIN 325MG EC TAB
#2: ETODOLAC 400MG TAB

2. Dose, frequency & route used | 3. Therapy dates
#1: 325 mg po qd | #1:
#2: 400 mg tid po prn | #2:

4. Diagnosis for use (indication) | 5. Event abated after use stopped or dose reduced?
#1: prophylaxis | #1: [N/A]
#2: pain | #2: [N/A]

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after reintroduction
#1: | #1: | #1: []
#2: | #2: | #2: []

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
ATENOLOL 50MG TAB
ASCORBIC ACID 500MG TAB
TERAZOSIN HCL 5MG CAP
PLEASE SEE ATTACHED

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [redacted]
VA MEDICAL CENTER 135 E. 38TH STREET
ERIE, PENNSYLVANIA 16504-1595 814-868-8661

2. Health professional? | 3. Occupation: PHARMACIST | 4. Reported to Mfr. [NO]
[YES]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box.

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JAN 18 2001

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CTU 135962



135962

ATTACHMENT PAGE

SUSPECT MEDICATION: ETODOLAC

DATE OF EVENT: 12/11/00

PATIENT ID: [REDACTED]

Section B. Part 6. Relevant Test/Laboratory Data Continued:

TEST: HGB RESULTS: L 10.6 g/dl H:18/L:14 COLLECTION DATE: 12/11/00@10:30
 TEST: HCT RESULTS: L 31.1 % H:52/L:42 COLLECTION DATE: 12/11/00@10:30
 TEST: RBC RESULTS: L 2.9 mil/ul H:6.1/L:4.7 COLLECTION DATE: 12/10/00@06:30
 TEST: HGB RESULTS: L 9.6 g/dl H:18/L:14 COLLECTION DATE: 12/10/00@06:30
 TEST: RDW RESULTS: 13.1 % H:14.5/L:11.5 COLLECTION DATE: 12/10/00@06:30
 TEST: HGB RESULTS: L 10.0 g/dl H:18/L:14 COLLECTION DATE: 12/9/00@05:30
 TEST: HCT RESULTS: L 29.0 % H:52/L:42 COLLECTION DATE: 12/9/00@05:30
 TEST: PLT RESULTS: L 70 thou/ul H:400/L:130 COLLECTION DATE: 12/9/00@05:30
 TEST: HGB RESULTS: L 10.4 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@15:00
 TEST: HCT RESULTS: L 30.5 % H:52/L:42 COLLECTION DATE: 12/8/00@15:00
 TEST: PLT RESULTS: L 84 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@15:00
 TEST: HGB RESULTS: L 10.5 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@10:30
 TEST: HCT RESULTS: L 30.8 % H:52/L:42 COLLECTION DATE: 12/8/00@10:30
 TEST: MCV RESULTS: H 97.5 fl H:94/L:80 COLLECTION DATE: 12/8/00@10:30
 TEST: PLT RESULTS: L 87 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@10:30
 TEST: HGB RESULTS: L 10.8 g/dl H:18/L:14 COLLECTION DATE: 12/8/00@05:30
 TEST: HCT RESULTS: L 31.2 % H:52/L:42 COLLECTION DATE: 12/8/00@05:30
 TEST: MCV RESULTS: H 97.5 fl H:94/L:80 COLLECTION DATE: 12/8/00@05:30
 TEST: PLT RESULTS: L 87 thou/ul H:400/L:130 COLLECTION DATE: 12/8/00@05:30
 TEST: INR RESULTS: 1.33 COLLECTION DATE: 12/7/00@16:14
 TEST: HGB RESULTS: L 11.4 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@16:14
 TEST: HCT RESULTS: L 33.2 % H:52/L:42 COLLECTION DATE: 12/7/00@16:14
 TEST: HGB RESULTS: L 12.0 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@15:00
 TEST: HCT RESULTS: L 35.0 % H:52/L:42 COLLECTION DATE: 12/7/00@15:00
 TEST: HGB RESULTS: L 13.5 g/dl H:18/L:14 COLLECTION DATE: 12/7/00@09:28
 TEST: HCT RESULTS: L 38.6 % H:52/L:42 COLLECTION DATE: 12/7/00@09:28
 TEST: PLT RESULTS: L 114 thou/ul H:400/L:130 COLLECTION DATE: 12/7/00@09:28

Section C. Part 10. Concomitant Drugs Continued

A & D OINT(60GM)
 MULTIVITAMIN CAP/TAB
 ASPIRIN 325MG EC TAB
 ACETAMINOPHEN 325MG TAB
 ETODOLAC 400MG TAB
 GENTAMICIN SULFATE 0.1% CREAM
 PHYTONADIONE INJ

12/07/00-12/07/00

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 JAN 22 2001

CTA 135962



3651295-3-00-01

Approved by FDA on 10/20/93

MedWatch

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Triage unit sequence # 135967

CDER

Page 1 of 2

A. Patient Information

1. Patient Identifier | 2. DOB: [redacted] | 3. Sex | 4. Weight
AGE: 81 yrs | MALE | 61.2 kg

B. Adverse Event or Product Problem

1. [X] Adverse Event [] Product problem
2. Outcomes attributed to adverse event
[] death [] disability
[X] life-threatening [] congenital anomaly
[X] Hospitalization [X] required intervention to prevent impairment/damage
initial or prolonged [] other

3. Date of event 11/18/00 | 4. Date of this report 11/22/00

5. Describe event or problem
GI REACTION, ANEMIA, black stools

6. Relevant test/laboratory data, including dates
PLEASE SEE ATTACHED

7. Other relevant history, including preexisting medical conditions
gi bleed with syncope, hypotension

C. Suspect Medication(s)

1. Name
#1: ASPIRIN

2. Dose, frequency & route used | 3. Therapy dates
#1: 325MG, UP TO 4, ORAL | #1: -11/18/00

4. Diagnosis for use (indication) | 5. Event abated after use stopped or dose reduced?
#1: PAIN | #1: [NO] *severe bleed -> surgery*

6. Lot # (if known) | 7. Exp. date | 8. Event reappeared after reintroduction
#1: | #1: | #1: []

9. (Not applicable to adverse drug event reports)

10. Concomitant medical products/therapy dates (exclude treatment)
LISINAPRIL 20MG TAB
DIGOXIN (LANOXIN) 0.25MG TAB
HYDROCHLOROTHIAZIDE 25MG TAB
POTASSIUM CHLORIDE 10MEQ SA CAP

D. Suspect Medical Devices

Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug

E. Reporter

1. Name, address & phone #: [redacted]
VA MEDICAL CENTER 135 E. 38TH STREET
ERIE, PENNSYLVANIA 16504-1596 814-868-8661

2. Health professional? [YES] | 3. Occupation | 4. Reported to Mfr.
[] | PHARMACIST | [NO]

5. If you don't want your identity disclosed to the Manufacturer, place an "X" in the box. [X]

Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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CTU 135967



135967

ATTACHMENT PAGE
PATIENT ID: [REDACTED]

SUSPECT MEDICATION: ASPIRIN

DATE OF EVENT: 11/18/00

Section B. Part 6. Relevant Test/Laboratory Data Continued:

TEST: HGB RESULTS: L 8.6 g/dl H:18/L:14 COLLECTION DATE: 11/18/00@19:30
 TEST: HCT RESULTS: L 24.5 % H:52/L:42 COLLECTION DATE: 11/19/00
 TEST: HGB RESULTS: L 9.3 g/dl H:18/L:14 COLLECTION DATE: 11/20/00@23:23
 TEST: HCT RESULTS: L 27.9 % H:52/L:42 COLLECTION DATE: 11/20/00@23:23
 TEST: HGB RESULTS: L* 7.4 g/dl H:18/L:14 COLLECTION DATE: 11/20/00@15:00
 TEST: HCT RESULTS: L* 21.4 % H:52/L:42 COLLECTION DATE: 11/20/00@15:00
 TEST: HGB RESULTS: L 9.3 g/dl H:18/L:14 COLLECTION DATE: 11/20/00@05:30
 TEST: HCT RESULTS: L 27.0 % H:52/L:42 COLLECTION DATE: 11/20/00@05:30
 TEST: HGB RESULTS: L* 7.8 g/dl H:18/L:14 COLLECTION DATE: 11/19/00@20:49
 TEST: HCT RESULTS: L* 22.5 % H:52/L:42 COLLECTION DATE: 11/19/00@20:49
 TEST: HGB RESULTS: L* 7.7 g/dl H:18/L:14 COLLECTION DATE: 11/19/00@05:30
 TEST: HCT RESULTS: L* 22.1 % H:52/L:42 COLLECTION DATE: 11/19/00@05:30

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CTA 135967



MEDWATCH Form

APPENDIX

Appendix

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems

FD-302 (Rev. 10-1-95)

Form number: 136381

A. Patient information

1 Patient identifier [Redacted]	2 Age at time of event: or Date of birth: [Redacted]	3 Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4 Weight 215.6 lbs or kg
------------------------------------	--	--	-----------------------------------

B. Adverse event or product problem

1 Adverse event and/or Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply):

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other

3 Date of event: 1/4/01

4 Date of this report: 1/24/01

5 Describe event or problem

Patient ordered Vioxx 50mg po bid x 3 days, then 50mg po qd. on 12/7/00. Patient also receiving ASA 325 mg po qd. On 1/4/01 pt had 7 episodes of coffee ground emesis. He also experienced abdominal pain during the episodes of emesis. On 1/4/01 pt also experienced a large black loose stool which was intractable (P). He was pale, with no further emesis, but continued to not feel well. His BP was 72/1? The patient reported he had not felt like eating for approximately 1 week & that food did not taste good to him. Patient was taken to ER. An upper endoscopy was performed which revealed an active antral gastric ulcer & 2 duodenal ulcers. Patient was admitted to hospital where he was treated with IV fluids, Pepid, Carafate and Priloseid. He was discharged on 1/9/01.

6. Relevant tests/laboratory data, including dates

BUN 5.2
Cr creatinine 1.5
Hemoglobin 9.4
Hematocrit 28.1
Platelets 578,000

on admission to hospital 1/4/01

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Upper extremity weakness 2° to cervical neck injury
Night orange exposure
PVD

C. Suspect medication(s)

1 Name (give labeled strength & manufacturer, if known)

#1 Vioxx 25mg tabs
#2 ASA 325 mg tabs

2 Dose, frequency & route used

#1 50mg po bid x 3 days
#2 325 mg po qd w/ food

3 Therapy dates (if unknown, give start/stop)

#1 12/7/00 - 1/4/01
#2 11/7/00 - 1/4/01

4 Diagnosis (or use indication)

#1 Arthritic neck pain
#2 PVD

5 Event abated after use stopped or dose reduced

#1 yes no not sure
#2 yes no not sure

6 Lot # (if known)

7 Exp. date (if known)

8 Event reappeared after reintroduction

#1 yes no not sure
#2 yes no not sure

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional
 lay user/patient
 other:

5. Expiration date

6. Model #

7. If implanted, give manufacturer

8. If explanted, give manufacturer

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer or

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[Redacted]

Pharmacy Services
Box 514

2. Health professional? yes no

3. Occupation

Pharmacist

4. Also reported to

manufacturer
 user/facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-0178

or FAX to:
1-800-FDA-0178

FDA Form 3500 (04/01)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

DSS

CTU 136381

CTU

JAN 26 2001



Health professionals of adverse events and product problems

FDA Use Only
Triage unit sequence # 136492

Page ___ of ___ **CDER** **CDER**

A. Patient information

1. Patient identifier 9877	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------	--	--	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	

3. Date of event: 11/28/00

4. Date of this report: 12/00

5. Describe event or problem

Admitted to MICU for hematemesis
Transfused 2u PRBC
Started sandostatin drip
Pt had stopped taking Prevacid
DIC NSAIDS, Ticlid
Continue Prevacid 30mg BID

6. Tests/laboratory data, including dates

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MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

8. Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

CTU 136492

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Aspirin
#2 Ibuprofen (OTC)

2. Dose, frequency & route used

#1 325mg QOD
#2 Unknown Qhs

3. Therapy dates (if unknown, give duration from to (or best estimate))

#1 _____
#2 _____

4. Diagnosis for use (indication)

#1 pain
#2 _____

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot # (if known)

#1 _____
#2 _____

7. Exp. date (if known)

#1 _____
#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply
#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____
#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional
 lay user/patient
 other: _____

5. Expiration date (mo/day/yr)

6. model # _____

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on: _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

_____ DSS
_____ JAN 29 2001

2. Health professional? yes no

3. Occupation RPH

4. Also reported to

manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



VOLUNTARY reporting
with professionals of adverse
events and product problems

Form approved: 02/01/00 Rev. 09/10/00 Expires: 03/01/03
FDA Use Only
FD-1089 (Rev. 10/2000)
134467

MEDWATCH
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of COEP COEP

A. Patient information

1. Patient identifier [redacted] In confidence	2. Age at time of event or Date of birth: <u>65</u>	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight [redacted] lbs or <u>55.5</u> kgs
--	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defect/malfunction)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (month/year): 11/21/00

4. Date of this report (month/year): 12/21/00

5. Describe event or problem

65yo white female = hx of peptic ulcer disease. Has been on Alendronate since beginning of year and Aspirin for months on 11/21/2000. On 11/21/2000, ID had sudden onset of severe nausea, followed by emesis of coffee ground material. Brought in to ER and given NG tube - drained coffee ground material. On 11/22/2000, [redacted] stated to vomit red blood. EGD done - found erosive gastritis and a 1cm, nonbleeding ulcer. On 11/23/2000 vomited 1 liter of blood taken to the OR to control bleeding. [redacted] received a partial gastrectomy to stop the bleeding. ID tolerated the OR and was discharged 12/7/2000.

3. Relevant tests/laboratory data, including dates

11/21 hb = 12.0
1/22 hb = 8.1 - 2 units RBC
11/23 hb = 9.0 - 3 units RBC
11/23 hb = 14.5

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Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato/renal dysfunction, etc.)

Past med Hx
① CAD
② HT per cholesteremic
③ osteoporosis
④ Arthritis
⑤ Hypertension
⑥ is 5 peritidolacc Dx

Allergies: Aspirin - Runny Nose

Current Meds:
Isosorbide (Imdur)
Zinc
Zocor
Calcium
multivite

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)

#1 Aspirin (Enteric coated) 325mg i qd
#2 Alendronate

2. Dose, frequency & route used

#1 325mg PO qd
#2 10mg PO qd

3. Therapy dates (if unknown, give duration) (month/year for best estimate)

#1 10/24/2000 - 11/21/2000
#2 2/2000 - 11/21/2000

4. Disables for use (indication)

#1 CAD
#2 osteoporosis

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply
#2 yes no doesn't apply

6. Let # (if known)

#1
#2

7. Exp. date (if known)

#1
#2

8. NDC # (for product problems only)

9. Concomitant medical products and therapy dates (exclude treatment of event)

Zinc 5/25 i qd
Imdur 60 1/2 tab po qd

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional
 lay user/patient
 other:

5. Expiration date (month/year)

6. Model #

7. If imported, give date (month/year)

8. If expired, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address
[redacted] Pharm D
Hospitals
[redacted] Rond

2. Phone #

3. Occupation
pharmacist

4. Also reporting to (month/year)

manufacturer
 user/facility
 distributor

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9707

FAX to: 1-800-FDA-0178

CTU 134467



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires: 12/31/00
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

136615

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 54 Years or Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 237.8 lbs or _____ kgs
-------------------------------------	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input checked="" type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 01/11/2001	4. Date of this report (mm/dd/yyyy) 01/29/2001
---	---

5. Describe event or problem

Patient admitted to PCU for observation for hematemesis. Patient had been taking Celebrex and BC Poeders regularly before admission. The day before the patient began vomiting blood and coffee grounds. Upper endoscopy confirmed med esophageal tear and Mallory-Weiss tear at GE function with evidence of gastritis in the stomach. Dx: gastritis secondary to NSAID use; N/V resultant of esophageal tear and Mallory-Weiss tear. Patient was discharged on Prevacid.

6. Relevant tests/laboratory data, including dates

NG tube removed coffee grounds and dark material. EGD showed mid esophageal tears and Mallory-Weiss tear 1/11/01 - H/H - 13.6/38.5 1/12/01 - H/H - 12.9/35.6

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Smokes 1/2 pack/day Denies alcohol and drug use h/o peptic ulcer disease and severe arthritis

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Celebrex / 200mg / Seale #2 BC Powders / 650mg ASA / Bloc	2. Dose/Frequency/Route used #1 200mg / qd / Oral #2 1 powde / qd or / Oral	3. Therapy date: (if unknown, give duration) #1 From - To (or best estimate) #2 -	5. Even abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1 arthritis #2 unknown	6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only) - -			
10. Concomitant medical products and therapy dates (exclude treatment of event) Possible Vioxx and hormones according to family. Strengths, length of use and dosing were never noted.			

D. Suspect medical device

1. Brand name	2. Type of device	3. Manufacturer name & address	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
5. Expiration date (mm/dd/yyyy)	6. model # MEDWATCH CTU	7. If implanted, give date (mm/dd/yyyy)	
8. If explanted, give date (mm/dd/yyyy)	9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no	10. Concomitant medical products and therapy dates (exclude treatment of event)	

RECEIVED
JAN 30 2001

DSS
JAN 30 2001

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]	2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			

CTU136615

RECEIVED

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-4791

1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



3347059-0-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

use by user-facilities, butors and manufacturers for MANDATORY reporting

Page 1 of 2

Page 2

Mfr report #	990007
UF/Dist report #	
FDA Use Only	

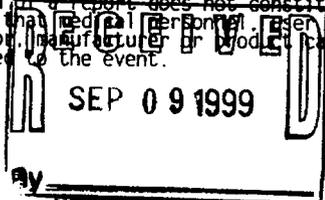
A. PATIENT INFORMATION			
1. Patient identifier #1 [REDACTED]	2. Age at event 89 Years or DOB: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight lbs or kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input checked="" type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product problem			
2. Outcomes attrib. to event <input type="checkbox"/> death (mo/day/yy) <input type="checkbox"/> life-threatening hospitalization - initial or prolonged		<input type="checkbox"/> disability <input type="checkbox"/> congen anomaly <input type="checkbox"/> required intervention to prevent perm impair/damage <input checked="" type="checkbox"/> other: _____	
3. Date of event 05/1999		4. Date of this Rept 06/15/1999	
5. Describe event or problem Patient experienced severe nausea and diarrhea. Dr. reduced dose to every other day. Patient said still having problems. Dr. told her to stop medication.			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexist. med. conditions Spoke with doctor's nurse, Joanne. She says Dr. did reduce dose to every other day, however, the patient did not call back nor did he tell her to stop medication. Patient is not scheduled for another appointment.			

C. SUSPECT MEDICATION(S)			
1. Name (give labeled strength & mfr/labeler, if known) #1 MiraLax			
2. Dose, frequency & route #1 17 gram daily PO		3. Therapy dates (if unk, give dur) #1 05/1999 - 06/1999	
4. Diagnosis for use (indication) #1 constipation		5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> N/A	
6. Lot # (if known) #1 _____		7. Exp. Date #1 _____	
9. NDC # for prod problems only #1 52268-800-02		8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> N/A	
10. Concomitant medical products and therapy dates			
D. SUSPECT MEDICAL DEVICE			
1. Brand name			
2. Type of device			
3. Manufacturer name & address			4. Operator of Dev. <input type="checkbox"/> Hlth Profes. <input type="checkbox"/> lay user/pat. <input type="checkbox"/> other:
6. Model# catalog# _____ serial# _____ lot# _____ other# _____			5. Expiration Date
9. Device available for evaluation? (Do not send to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to mfr on			7. If implanted, give date
10. Concomitant medical products and therapy dates			8. If removed, give date

E. INITIAL REPORTER			
1. Name, address & phone # P.O. Box [REDACTED] (daughter) Phone: [REDACTED]			
2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> Junk	

MED INFO ASSOC Submission of a report does not constitute an admission that the person, user facility, distributor, manufacturer or product caused or contributed to the event.

Facsimile Form 3500A



Individual Safety Report



3347059-0-00-02

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

F. FOR USE BY USER FACILITY/DISTRIBUTOR-DEVICES ONLY

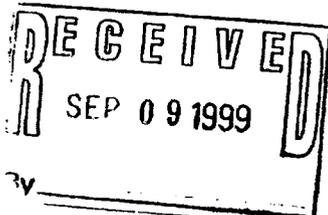
1. Check One [] user facility [] distributor		2. UF/Dist report number	
3. User facility or distributor name/address			
4. Contact person		5. Phone Number	
6. Date user facility or distributor became aware of event		7. Type of report [] initial [] follow-up #	8. Date of this Report
9. Approximate age of device	10. Event problem codes (ref. to coding manual) patient code [] - [] - [] device code [] - [] - []		
11. Report sent to FDA? [] yes [] no (mo/day/yr)	12. Location where event occurred [] hospital [] outpatient [] home [] diagnostic facil. [] nursing home [] ambulatory [] outpatient [] surgical facility [] other: specify		
13. Report sent to Mfr. [] yes [] no (mo/day/yr)			
14. Manufacturer name/address			

G. ALL MANUFACTURERS

1. Contact office - name/address Mark vB. Cleveland, Ph.D Braintree Laboratories, Inc. P.O. Box 850929 60 Columbian Street Braintree, MA 02185		2. Phone number (781) 843-2202	
4. Date Rec'd by Mfr. 06/04/1999		3. Report Source (check all that apply) [] foreign [] study [] literature [X] consumer [] health [] professional [] user facility [] company [] representative [] distributor [] other:	
6. If IND. protocol #	5. (A)NDA# 20-698 IND# PLA#		
7. Type of report (check all that apply) [] 5-day [] 15-day [] 10-day [X] periodic [] Init [] follow-up #	pre-1938 [] yes OTC [] yes product		
9. Mfr. report number 990007	8. Adverse event term(s) nausea, diarrhea		

H. DEVICE MANUFACTURERS ONLY

1. Type of reportable event [] death [] serious injury [] malfunction (see guid.) [] other:	2. If follow-up, what type? [] correction [] additional information [] response to FDA request [] device evaluation		
3. Device evaluated by mfr? [] not returned to mfr. [] yes [] eval summ attach [] no (attach page to expl. why not) or provide code:	4. Device manufacture date (mo/yr)	5. Labeled for single use? [] yes [] no	
6. Evaluation codes (refer to coding manual) method [] - [] - [] - [] results [] - [] - [] - [] conclusions [] - [] - [] - []			
7. If remedial action initiated, check type [] recall [] notification [] repair [] inspection [] replace pat. monitor [] relabel. [] modification/adjustment [] other:		8. Usage of device [] initial use of device [] reuse [] unknown	
10. [] Additional mfr. and/or narrative	9. If action reported to FDA under 21 USC 360i(f), list correction/removal rep. num.:		
11. [] Corrected Data			





LUNTARY reporting
professionals of adverse
and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31/00
See CMB statement on reverse

FOA Use Only
Triage unit sequence # 136667
Takeda for Journal of JGIM

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 86 Years
3. Sex: female male
4. Weight: 139.4 lbs or ___ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death 01/14/2001 (mm/dd/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: 12/25/2000 (mm/dd/yyyy)
4. Date of this report: 01/29/2001 (mm/dd/yyyy)

5. Describe event or problem:
Patient was admitted for anemia secondary to GI bleed. The patient was diagnosed with a perforated ulcer -gastric-. The perforation was repaired on 12/27/2000. At this point the Vioxx and ASA were discontinued. The site was drained again on 1/11/2001. The patient expired on 1/14/2001.

6. Relevant tests/laboratory data, including dates:
H/H -12/25 - 8.8/25.6 ScCr - 12/25 - 1.8
1/2 - 1.0 1/14 -
2.1 12/27 - positive for staph. capitis
1/11 - positive for MRSA

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
patient has diabetes, high blood pressure, GERD, arthritis, cardiac dysrhythmia, depression h/o MI

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler)
#1 Vioxx / 50mg / Merck
#2 ASA / 81mg /

2. Dose/Frequency/Route used
#1 / / Oral
#2 / / Ora

3. Therapy dates (if unknown give duration):
#1 From - To (or best estimate)
#2

4. Diagnosis for use (separate indications with commas):
#1 arthritis
#2 post MI

5. Event abated after use stopped or dose reduced:
#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot # (if known): #1 #2
#1 #2

7. Exp. date (if known): #1 #2

8. Event reappeared after reintroduction:
#1 yes no doesn't apply
#2 yes no doesn't apply

9. NDC # (for product problems only): - -

10. Concomitant medical products and therapy dates (exclude treatment of event):
Prevacid, Klonopin, Lasix, Ativan, Lanoxin, Vasotec, Glucophage, Glucotrol, Verapamil, Albuterol, Rfemerol, Trazadone, Macrob

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device:
 health professional
 lay user/patient
 other

5. Expiration date (mm/dd/yyyy)
6. model # JAN 30 2001
7. If implanted, give date (mm/dd/yyyy)
8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA):
 yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]
Dr. [redacted] Hospital [redacted] [redacted]
United States

2. Health professional? yes no
3. Occupation: Pharmacist
4. Also reported to:
 manufacturer
 user/facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane, Rockville, MD 20852-9787
or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



3657377-4-00-02

136667

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5

C10. Concomitant medical products and therapy dates continued

id, Ambien: Meds at admission

D10. Concomitant medical products and therapy dates continued

DSS

JAN 31 2001

136667

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.



3657833-9-00-01

VOLUNTARY reporting health professionals of adverse events and product problems

FDA Use Only

Triage unit sequence # 136711

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

UDON

A. Patient information

1. Patient identifier [redacted] 2. Age at time of event: 59 3. Sex: [X] female 4. Weight: ? lbs

B. Adverse event or product problem

1. [X] Adverse event and/or [] Product problem 2. Outcomes attributed to adverse event: [X] hospitalization - initial or prolonged

3. Date of event: 5/21/00 4. Date of this report: 1/25/01

5. Describe event or problem: 59yo F who was transferred from the Savannah Mental Health Unit to the medical floor on 5/21/00 because of pneumonia & respiratory failure. He was diagnosed with a probable non Q-wave MI of Aggrastat, ASA & Lovex were started for management on 5/21. He then developed @ on bleeding, acute GI BLEED (bunked coffee grounds like substance) & a ↓ B/P bleeding from @ ear. Apped p DIC. aggrastat

6. Relevant tests/laboratory data, including dates. Table with columns for dates (5/20, 5/21, 5/22, 5/23, 5/24, 5/25, 5/26, 5/28, 5/30) and rows for Hb, Ht, Hct.

DSS FEB 01 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.): NKDA (cept eggs), EOPD, Chronic anxiety, Depression, Chronic gastritis, Ongoing emphysema, Hx of CAD

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known): #1 Aggrastat 12.5mg/50ml (Inveco) #3 ASA 3.5mg EC (G.D. Searle) #2 Lovexox 80mg (Aventis Pharmaceuticals) 2. Dose, frequency & route used: #1 12.5mg/50ml IV qd #3 PO 325mg qd #2 64mg bid SQ 3. Therapy dates: #1 5/21 (#3) 5/21 #2 5/21 4. Diagnosis for use (indication): #1 #3 ? MI 5. Event abated after use stopped or dose reduced: #1 [X] yes [] no [] doesn't apply #2 [X] yes [] no [] doesn't apply 6. Lot # (if known): #1 #2 7. Exp. date (if known): #1 #2 8. NDC # (for product problems only): 0000-637-13 (Aggrastat) 10. Concomitant medical products and therapy dates (exclude treatment of event): Neurontin, Vellonin, Salmetrol, Insulin, Flay 110 (5/21-5/24) (5/21-1/13) (5/21-5/24) started prior to admission

D. Suspect medical device

1. Brand name: N/A 2. Type of device: 3. Manufacturer name & address: RECEIVED JAN 31 2001 MEDWATCH CTU 4. Operator of device: [] health professional [] lay user/patient [] other: 5. Expiration date (month/year): 6. model #: 7. If implanted, give date (month/year): 8. If explanted, give date (month/year): 9. Device available for evaluation? (Do not send to FDA) [] yes [] no [] returned to manufacturer on (month/year): 10. Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

1. Name & address: [redacted] phone #: [redacted] 2. Health professional? [X] yes [] no 3. Occupation: Pharmacist 4. Also reported to: [] manufacturer [] user facility [] distributor 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. []

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

PLEASE TYPE OR USE BLACK INK

CTV136711



3658235-1-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

or VOLUNTARY reporting
by health professionals of adverse
events and product problems

CLF

Form Approved: OMB No. 0910-0291 Expires: 12-31-00
See OMB statement on no. 0910

FDA Use Only
Trace # and sequence #
136797

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 76 Years or Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------------	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	

3. Date of event (mm/dd/yyyy): 12/18/2000

4. Date of this report (mm/dd/yyyy): 01/31/2001

5. Describe event or problem

Patient is a 76 year old male with history of CAD, angioplasty with stent, gerd, hypertension, diabetes, atrial fib, and gout who presents to ER on 12/18/00 with complaint of swelling in great toes for the last 3 weeks. While being evaluated patient had syncopal episode and was found to be orthostatic. BP was 138/60 supine, 142/85 sitting and 70/50 standing. Upon further questioning the patient stated that he has been having black tarry stools for the last 2 weeks. has been "lightheaded" the last 2 days. Patient has been taking more aspirin than once per day prescribed. Patient's current medications include isosorbide, metoprolol, amitriptyline, and aspirin. He was admitted. EGD was performed which showed two small gastric ulcers. Aspirin was discontinued. ~~amitriptyline and aspirin~~

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Aspirin EC / 325mg /	2. Dose/Frequency/Route used #1 325mg / qd / Oral	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 07/01/2000 - 12/18/2000
#2 / /	#2 / /	#2 -

4. Diagnosis for use (separate indications with commas)

#1 _____

#2 _____

5. Event abated after use stopped or dose reduced?

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)

#1 #1

#2 #2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 -

#2 -

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other: _____

5. Expiration date (mm/dd/yyyy)

6. Model # _____

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]

2360cki VA Medical Center 5000 W National Ave

Milwaukee Wisconsin FEB 02 2001

United States

2. Health professional? yes no

3. Occupation Pharmacist

4. Also reported to

manufacturer

user facility

distributor

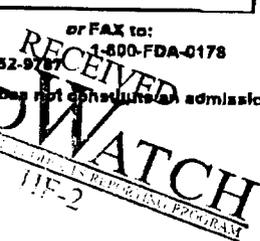
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Submission of this report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU136797



Individual Safety Report

VOLUNTARY reporting
health professionals of adverse
events and product problems

FDA Use Only

Triangle with
sequence # **136839**



3658423-4-00-01

Page ___ of ___

C.D.E.R.

A. Patient information

1. Patient Identifier 11065263	2. Age at time of event 90	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ___ lbs or ___ kgs
In confidence		Date of birth: _____	

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) **11/11/00**

4. Date of this report (mo/day/yr) **11/14/00**

5. Describe event of problem

Upper GI bleed; Multiple erosions in fundus - some oozing blood.

GI consult impression: NSAID Gastropathy

∴ D/C Aspirin, Celecoxib, started Pantoprazole.

8. Relevant tests/laboratory data, including dates

11/11 Hct = 29.9

11/11 Hgb = 9.9

9. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKA

PMH: DVT, DM, CAD, HTN, Palpitations

C. Suspect medication(s)

1. Name (give labeled strength & mlr/labeler, if known)

#1 **Celecoxib (200mg po qd)**

#2 **ASA (dose not specified qd)**

2. Dose, frequency & route used

#1 **200mg po qd**

#2 **? po qd**

3. Therapy dates (if unknown, give start or stop date)

#1 **Took PTA (at least several months)**

#2 " " "

4. Diagnosis for use (indication)

#1 **Arthritis**

#2 **Daily Cardiac Prophylaxis**

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. NDC # (for product problems only)

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

Captopril 60mg po qd, Rosiglitazone 4mg po qd, Enalapril 10-125mg po qd, folic acid, Multi-Vitamin, NPH 10 Units SQ qAM, Metoprolol 25mg po bid, ACE 25mg po qd, Isosorbide 30mg po qd, Warfarin

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device:

health professional

lay user/patient

other:

5. Expiration date (mo/day/yr)

6. model # **RECEIVED**

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & address

[redacted] Health Hospital

2. Health professional?

yes no

3. Occupation

Clinical Pharmacist

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

FAX to: 1-800-FDA-0178

CTU 136839

Individual Safety Report



3659716-7-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved CMB No. J910-0291 Expires 12-31/94
See OMB statement on reverse

FDA Use Only

Triage unit
sequence # **136875**

THE FDA MEDICAL DEVICE IS REGULATORY DIVISION

Page of

A. Patient information

1. Patient identifier 00-115 <small>In confidence</small>	2. Age at time of event: or Date of birth: [REDACTED]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 149 lbs or kgs
--	--	---	--

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other:

3. Date of event (mo/day/yr): **10/15/00**

4. Date of this report (mo/day/yr): **12/18/00**

5. Describe event or problem

Pt. presented to ER w/ c/o Abdominal pain (upper) for several days.
During hospitalization, an endoscopy was performed. (Proximal Gastric Superficial ulceration).

6. Relevant tests/laboratory data, including dates

Endoscopy done 10/17/00.

DSS
FEB 05 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Flu Vaccine Allergy.
HTN, Hyperlipidemia,
Skin Cancer
Hx Gastric Ulcer
CTU136875

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)		3. Therapy dates (if unknown, give date on file to start/stop)	
#1 Enteric Coated Aspirin		#1 PTA	
#2 Celebrex (started taking 700mg QD x 7-10 days)		#2 recently PTA	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 81mg PO QD		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 then ↑ 200mg PO BID		#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication)		3. Event reappeared after reintroduction	
#1 Arthritis		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 Arthritis		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 unknown		#1 unknown	
#2 unknown		#2 unknown	
9. NDC # (for product problems only)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
Lipitor 20mg QD, Norvasc 5mg QD, Atenolol 50mg BID			

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device:
 health professional
 lay user/patient
 other

5. Expiration date (mo/day/yr)

7. If implanted, give date (mo/day/yr)

8. If exsplanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[REDACTED] Hospital Ave.

2. Health professional? yes no

3. Occupation
Pharmacist

4. Also reported to:
 manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

FDA Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

Individual Safety Report



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LATORY SAFETY
or use by user-facilities,
ors and manufacturers for
NDATORY reporting

Approved by FDA on 09/25/95

Mfr report #	001-0991-970964
LFD/Dir report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 11

A. Patient information

1. Patient identifier	2. Age at time of event: 63 Y	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 230 lbs or kgs
In confidence			

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or	<input type="checkbox"/> Product problem (e.g., defects/malfunctions)
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input checked="" type="checkbox"/> other: MED SIGNIFICANT
3. Date of event (mo/day/yr) 08/24/97	4. Date of this report (mo/day/yr) 01/22/01

5. Describe event or problem

Patient is a 63 year old male with diabetes and a history of diabetic neuropathy, autonomic neuropathy, blindness, hypothyroidism, a foot ulcer, impotence, multiple diabetic complications and a sister with a history of lupus. He began taking Rezulin (troglitazone) 200mg daily on 09APR97. Troglitazone was increased to 400mg daily in MAY97. On approximately 09SEP97, the patient experienced malaise and fatigue. His physician also noticed that he was yellow in appearance. Lab testing revealed abnormal LFT's and a bilirubin of 7. Transaminases were in the 1000-1500's. A liver biopsy showed "bridging necrosis." The patient was negative for both hepatitis B and C. Both troglitazone and lovastatin were discontinued on 09SEP97. No further information was provided. The clinical outcome is unknown. Concomitant medications include Mevacor (lovastatin), insulin, Synthroid (levothyroxine sodium), Glynase (glibenclamide), monopril (fosinopril sodium), and Lipitor (atorvastatin). This case was reported by a physician via a company representative. Additional

6. Relevant tests/laboratory data, including dates

26AUG97 Chest x-ray (CXR) revealed the following: "There is a focal infiltrate in the lower left lobe which may be chronic in nature...No evidence of congestive failure is noted. Cardiomeastinal silhouette appears to be within normal limits."
27AUG97 Electrocardiogram (ECG) revealed normal sinus rhythm and left anterior fascicular block.
28AUG97 Carotid Doppler ultrasound revealed

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Caucasian
No known allergies
Non-smoker, non-drinker
Obesity
Sister has history of lupus
Family history of heart disease and diabetes

Fatty liver
Heart/vascular disease (unspecified)
Diabetic neuropathy

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeled, if known)	
#1 REZULIN 400MG TABLET (TROGLITAZONE)	
#2 ASA (ACETYSALICYLIC ACID)	Cont.
2. Dose, frequency & route used	
#1 200 mg (QAM), Per oral	3. Therapy dates (if unknown, give duration) (mo/da/yr)
#2 UNK, Per oral	#1 04/09/97 - 05/20/97
	#2 Unk - 12/06/97
4. Diagnosis for use (indication)	
#1 INSULIN DEPENDENT DIABETES MELLITUS	5. Event abated after use stopped or dose reduced
#2 UNK	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	
#1 UNK	7. Exp. date (if known)
#2 UNK	#1 UNK
	#2 UNK
9. NDC # - for product problems only (if known)	
#1	#2

10. Concomitant medical products and therapy dates (exclude treatment of event):

1) MEVACOR (LOVASTATIN) Unk - 09/10/97
2) HUMULIN 70/30 (INSULIN HUMAN INJECTION, Unk)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
REGENER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42ND STREET NEW YORK NY 10017 (-Printing Unit)	(212) 573-3129
4. Date received by manufacturer (mo/day/yr) 01/15/01	3. Report source (check all that apply)
6. If IND, protocol #	<input type="checkbox"/> foreign
7. Type of report (check all that apply)	<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	<input checked="" type="checkbox"/> consumer
<input type="checkbox"/> Initial <input checked="" type="checkbox"/> follow-up # 11	<input checked="" type="checkbox"/> health professional
9. Mfr. report number 001-0991-970964	<input type="checkbox"/> user facility
	<input checked="" type="checkbox"/> company representative
	<input type="checkbox"/> distributor
	<input type="checkbox"/> other:

8. Adverse event term(s)

1) ESOPHAGEAL VARICES
2) CYTOMEGALOVIRUS POSITIVE
3) CIRRHOSIS
4) HEPATIC ENCEPHALOPATHY
5) HEPATOMEGALY
6) UPPER GI BLEEDING

E. Initial reporter

1. Name, address & phone #

[Redacted] ESQ
[Redacted] DSS
USA
Phone # [Redacted] JAN 31 2001

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation N/A	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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B. Adverse event or product problem

B.5 Describe event or problem (Cont...)

information is being requested.

Further review of the case on 20OCT97 revealed that the start date of troglitazone was 09APR97, and not MAY97 as previously indicated in box C3 of the MedWatch.

Follow-up information received from the physician on 05AUG98 reveals that the patient is scheduled to receive a liver transplant. Additional information has been requested.

Follow-up information received from the physician on 09SEP98 provided no new information. The patient has not yet recovered and is still scheduled for a liver transplant. Additional information has been requested.

Follow-up information received from a consumer on 03DEC98 reveals that the patient has been taken off the liver transplant list because he is not a likely candidate due to his age and other illnesses. The patient is no longer jaundiced, however, he has not yet recovered. This additional information was reported by the patient's wife. Additional information is being requested.

Follow-up information received from the physician 01MAR99 relates that the Caucasian patient also experienced hepatitis, hepatomegaly, upper gastrointestinal hemorrhage, cirrhosis and portal hypertensive gastropathy, all considered medically significant, ascites, left kidney cyst, enlarged prostate, gastritis and a positive anti-nuclear antibody (ANA) titer. On 04SEP97, the patient presented with pruritis, jaundice, splenomegaly and hepatomegaly while taking Rezulin (troglitazone) for 5 months. Laboratory tests performed on 11SEP97 revealed the following: serum glutamic oxaloacetic transaminase (SGOT) = 860, serum glutamic pyruvic transaminase (SGPT) = 1496, alkaline phosphatase (Alk-P) = 120, total bilirubin = 5.9, and hemoglobin = 14. On 11SEP97, a computed tomography (CT) of the abdomen and pelvis revealed the following: left renal cyst, diffusely atrophic pancreas, no evidence of hepatosplenomegaly, no discrete abnormalities of the liver, no dilation of the biliary tree, and no intra-abdominal masses. A liver biopsy performed on 18SEP97 revealed the following: "pronounced subacute hepatitis including hydropic degeneration, acidophilic bodies, lymphoplasmacytic infiltrate within the lobules and portal tract as well as areas of bridging necrosis. Occasional eosinophils present within the inflammatory infiltrate and sinusoids. The histologic appearance is variable and could be consistent with drug etiology. However, acute viral hepatitis cannot be excluded on histologic bases alone." On 06NOV97, laboratory tests revealed the following: albumin = 3.30 mg/dL (3.60-4.60 normal), total bilirubin = 7.25 mg/dL (0.20-1.10 normal), SGOT = 117 IU/L (1.00-45.0 normal), SGPT = 165 IU/L (1.00-44.0 normal), Alk-P = 228 U/L (30-140 normal), lactic dehydrogenase (LDH) = 175 IU/L (96.0-234 normal) and gamma-glutamyl transpeptidase (GGTP) = 1040 U/L (1.00-78.0 normal). On 25FEB98, laboratory tests revealed the following: total bilirubin = 1.73 mg/dL, Alk-P = 357 U/L, GGT = 312 U/L, SGOT = 60 U/L and SGPT = 65 U/L. On 25MAR98, laboratory tests revealed the following: total bilirubin = 1.3 mg/dL (0.2-1.3 normal), Alk-P = 313 U/L (38-126 normal), GGT = 272 U/L (8-78 normal), SGOT = 56 U/L (15-46 normal), SGPT = 68 U/L (7-56 normal), positive anti-nuclear antibody titer of 1:80 (<1:40 normal) and mitochondrial antibodies of <1:20 (<1:20 negative). Laboratory tests performed on 10SEP98 revealed the following: total bilirubin = 0.9 mg/dL, Alk-P = 158 U/L, SGOT = 33 U/L and SGPT = 47 U/L. An abdominal ultrasound performed on 18SEP98 revealed the following: evidence of cirrhosis with splenomegaly, normal hepatopetal portal blood flow, moderate ascites, and poorly visualized hepatic veins likely due to cirrhosis. On 22SEP98, the patient underwent an esophagogastroduodenoscopy, which revealed distal esophageal varices, portal hypertensive gastropathy, and antral gastritis with polypoid appearing mucosa. The patient underwent a successful variceal band ligation of three dominant distal esophageal varices. The patient also had a history of a fatty liver and heart/vascular disease.

Follow-up information received from the physician on 23MAR99 relates that the patient had severe underlying liver problems prior to Rezulin (troglitazone). The reporter also stated that troglitazone "put the patient over the edge." The reporting physician referred us to another physician who is familiar with this patient, and is a liver specialist.

Additional information received from the liver specialist on 24MAR99 relates that the patient developed drug induced fulminant hepatitis, and cirrhosis because of the reaction to troglitazone. The patient experienced two life-threatening episodes of esophageal varices, which led to hypotensive crises. The patient also developed portal hypertension, remained jaundiced for nine months, and developed subtle hepatic encephalopathy manifested by disorientation and insomnia. The patient is now clinically stable with decompensated cirrhosis.

Follow-up information received from the physician on 26MAY99 related that on 10SEP97, the patient presented to the hospital with general malaise and a 2 to 3 week history of not feeling well. On 26AUG97, laboratory tests revealed the following: creatinine = 1.40 mg/dL (0.60-1.20), glucose = 444 mg/dL (65-115), total bilirubin = 2.03 mg/dL (0.20-1.1), direct bilirubin = 0.86 mg/dL (0-0.20), AST = 463 IU/L (1-45), ALT = 1082 IU/L (1-44), LDH = 392 IU/L (95-234), GGTP = 257 U/L (1-78), serum ferritin = 2104 mcg/L (10-107) and iron = 181 mcg/L (45-145). On 10SEP97, an abdominal ultrasound revealed bilateral renal parenchymal

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cysts, a mildly prominent spleen, and no evidence of cholelithiasis or ductal dilation. On 10SEP97, a chest and abdominal X-ray revealed nonspecific dilation of a redundant loop of the sigmoid colon, no evidence of obstruction and no acute chest pathology. An echocardiogram performed on 11SEP97 was normal other than a non-dilated left ventricle with concentric left ventricular hypertrophy and normal systolic function and minimal mitral annular calcification. Laboratory tests performed on 12SEP97 revealed the following: ferritin = 2166 ng/mL (18-440). On 16SEP97, laboratory tests revealed the following: creatinine clearance = 212 mL/min (107-139) and 24 hour creatinine clearance = 3360 mg/24hr (1000-1900). Laboratory tests performed on 25SEP97 revealed the following: positive cytomegalovirus (CMV) of 2.91 (0-0.90), positive anti-histone antibody, positive anti-smooth muscle antibodies of 40 (<20), positive Epstein-Barr virus of 409 (0-100) and serum ferritin = 1629 mcg/L (23-233). The patient was hospitalized on 06DEC97 for vomiting bright red blood, and was diagnosed with aspirin-induced gastrointestinal bleed. An esophagogastroduodenoscopy performed on 06DEC97 revealed diffuse gastritis with erosions, distal esophageal ulcer with surrounding Mallory Weiss tears, diffuse duodenitis, sliding hiatus hernia and esophageal motility disorder. The patient also has a history of carotid stenosis, hypertension, peripheral vascular disease, elevated cholesterol and bilateral lower extremity claudication. Concomitant medications also included aspirin (acetylsalicylic acid) and Humulin 70/30 insulin.

Follow-up information received on 04AUG99 from the physician included additional procedures from 26AUG97 through 28AUG97 and copies of part of the hospital records from 10SEP97 through 11SEP97. These records indicate that the patient also experienced lightheadedness, palpitations and elevated glucose after taking troglitazone. On 26AUG97, a chest x-ray revealed the following: "There is a focal infiltrate in the lower left lobe which may be chronic in nature...No evidence of congestive failure is noted. Cardiomedial silhouette appears to be within normal limits." On 27AUG97, an electrocardiogram (ECG) revealed "normal sinus rhythm and left anterior fascicular block." On 28AUG97, a carotid Doppler ultrasound revealed the following: "Moderate 60-79% stenosis proximal right internal carotid artery." On 10SEP97, the patient was seen by his private physician, who found the patient to have abnormal liver enzymes and an elevated glucose. The patient was sent to the emergency room for further evaluation and hospitalization was advised. Although the patient had no complaints, his physician was sending him for further evaluation because of lightheadedness, jaundice and fatigue. The patient was sent to the emergency room. On 11SEP97, the patient was evaluated at the hospital for increased abdominal girth. It was noted at that time that the patient has complained of palpitations over the past two weeks, but without shortness of breath or chest pain. The patient has had no syncope and has no cardiac history. The impression of the consulting physician was that the "palpitations [were] possibly due to arrhythmia's." The patient's clinical outcome is unknown. The patient has no known allergies. Concomitant medications also included Reglan (metoclopramide).

Follow-up information received on 03NOV00 from an attorney relates that the patient developed colon polyps, requiring intervention, esophageal varices, considered medically significant, in addition to colopathy, an incompetent lower esophageal sphincter, tortuous colon, chronic constipation, gastropathy, Lyme disease, shortness of breath, became sweaty, belching, an elevated gamma-glutamyl transpeptidase, decreased international normalized ratio, hemorrhoids, and carotid stenosis after receiving troglitazone. On 24AUG98, the patient visited his physician in follow-up for diabetes and liver disease, "[side effect] of troglitazone." The physician's notes indicate that the "patient has improved" and was on insulin, with improved compliance. On 01FEB99, an esophagogastroduodenoscopy (EGD)/variceal band ligation revealed distal esophageal varices with successful band ligation times two (with no signs of residual varices) and portal hypertensive gastropathy. On 02JUN99, the patient visited his physician complaining of a red, hot, and swollen area on the left medial upper arm diagnosed as a maculae due to Lyme disease. A Western blot that day was positive for Lyme disease antibodies and the patient was diagnosed with Lyme disease. On 27AUG99, an EGD/gastric polypectomy revealed gastric antral polyps (snare excised), portal hypertensive gastropathy, status/post variceal band and ligation for esophageal varices with no evidence of active varices at that time. On 22NOV99, the patient underwent a colonoscopy with polypectomy which revealed a splenic flexure and sigmoid colon polyps, which were excised. Findings also included a redundant tortuous colon secondary to chronic constipation and underlying motility disorder from diabetes and internal hemorrhoids. On 27MAR00, lab testing revealed the patient's hemoglobin = 10g/dL (12.5-17), hematocrit = 31.5% (36-50), mean corpuscular volume = 77 fL (80-98), mean corpuscular hemoglobin = 24.3 (27-34), and mean corpuscular hemoglobin concentration = 31.7 g/dL (32-36). On 10APR00, the patient visited his physician for pre-op for carotid stenosis. On 12JUN00, the patient underwent a colonoscopy, which revealed colonic polyps which were excised and sent for pathology, right sided portal hypertensive colopathy and prominent erythematous ileocecal valve, redundant colon, and large internal hemorrhoids with prominent rectal veins. On that date, a EGD revealed status/post esophageal variceal band ligation with no evidence of recurrent varices, diffuse gastritis with antral predominance consistent with portal hypertensive gastropathy, large antral and pre-pyloric polypoid lesions (hyperplastic on prior pathology), and an incompetent lower esophageal sphincter. The patient's clinical outcome is unknown.

Follow-up information was received from an attorney on 18DEC00. Information received included medical records, physician's notes, hospital records, and laboratory procedures. In SEP97, the patient was diagnosed with liver failure, considered medically significant and

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thought to be secondary to troglitazone therapy, and was near death awaiting a liver transplant. On 18SEP97, the patient was found to have bilateral superficial femoral arterial occlusion. In DEC97, the patient experienced upper GI bleed. At that time, an esophagogastroduodenoscopy (EGD) was performed and revealed a Mallory-Weiss tear. The patient was subsequently treated with Zantac (ranitidine hydrochloride). Another EGD was performed on 06DEC97. In the distal esophagus, there was a large 1.5 cm ulceration. Surrounding the ulceration were two small linear tears, 5 to 6 mm in length with associated exudate. A small to moderate sized sliding hernia was also noted. There was diffuse erythema, edema, and easy friability noted throughout the entire stomach. A snakeskin-like pattern was noted on the mucosa. In the body and the antral region, there were multiple erosions. The duodenal bulb was noted as having a patchy exudate extending down into the second and third portions of the duodenum with associated erythema and edema notable for duodenitis. The physician noted that the patient had an esophageal motility disorder. On 18SEP98, an abdominal ultrasound was performed and revealed evidence of cirrhosis with splenomegaly and moderate ascites. On 01DEC98, a pre-pyloric tissue biopsy revealed a hyperplastic polyp showing severe acute and chronic inflammation with focal ulceration and intestinal metaplasia. An antral tissue biopsy showed pronounced erosion and occasional dilated glands consistent with hyperplastic polyp. The patient underwent a colonoscopy with polypectomy on 22NOV99 due to rectal bleeding and constipation. There were two polyps found and each was snare excised. In JUN00, cecum and sigmoid colon biopsies revealed tubular adenoma. The patient spontaneously recovered from the liver failure. His clinical outcome from all other adverse events is unknown.

Follow-up information was received from an attorney on 15JAN01 in the form of medical records from two hospitals. The patient also experienced an esophageal ulcer, hematemesis, being hypotensive, worsening of carotid stenosis, all leading to hospitalization, as well as atrophic pancreas. Troglitazone was discontinued on 11SEP97 while the patient was in the hospital. The patient was admitted to the hospital through the emergency room on 05DEC97 after experiencing a self-limited episode of hematemesis likely secondary to aspirin (acetylsalicylic acid) induced gastropathy. The patient had evidence of ongoing hepatic insufficiency, no severe coagulopathy, but hypoalbuminemia was present (albumin level was 2.4). An EGD on 06DEC97 showed a large esophageal ulcer with surrounding Mallory Weiss (MW) tears at the gastroesophageal junction, a sliding hiatal hernia, diffuse gastritis with erosions, diffuse duodenitis, and no evidence of an active upper gastrointestinal (UGI) hemorrhage. His hemoglobin (Hgb) was 10.6 and his hematocrit (HCT) was 31.0. He was discharged on 08DEC97. On 08SEP98 the patient vomited blood and was taken via ambulance to the emergency room where he was treated and then admitted to the hospital. In the hospital he was hypotensive with a systolic blood pressure (BP) of 80. Laboratory test results revealed the following: Hgb 10.6, indices normal, glucose 355, albumin 2.6, alkaline phosphatase (ALK-P) 226. He received two units of packed red blood cells on admission. His systolic BP increased to 105 with intravenous fluids. A nasogastric (NG) tube was put in place. An EGD done on 09SEP98 showed massive upper GI bleeding secondary to esophageal varices, likely caused by liver cirrhosis and portal hypertension. A chest x-ray (CXR) on 09SEP98 was unremarkable. On 22SEP98, the patient underwent an EGD for esophageal varices and portal hypertensive gastropathy with variceal band ligation the results revealed distal esophageal varices, portal hypertensive gastropathy, and antral gastritis with polypoid appearing mucosa. Biopsies of the gastric antrum showed moderate chronic active gastritis with no metaplasia or dysplasia, and no definite Helicobacter pylori. The patient underwent a second EGD with variceal band ligation on 13OCT98. This revealed distal esophageal varices; successful second procedure for variceal band ligation of dominant esophageal varices; portal hypertensive gastropathy; and antral predominant gastritis. On 01DEC98, an EGD was performed for esophageal varices, saline assisted polypectomy, and a snare polypectomy, which showed antral polypoid lesions; portal hypertensive gastropathy; distal esophageal varices, Grade I to II with no evidence of active or recent hemorrhage; and a sliding hiatal hernia. On 01FEB99 an EGD/variceal band ligation revealed distal esophageal varices and successful band ligation times two with no signs of residual varices, and portal hypertensive gastropathy and on 27AUG99 an EGD/gastric polypectomy revealed gastric antral polyps that were snare excised, portal hypertensive gastropathy, status/post variceal band ligation for esophageal varices with no evidence of active varices. A CXR on 11APR00 revealed mild cardiomegaly. The patient was admitted to the hospital on 17APR00. A carotid Doppler showed 90% right carotid stenosis and 60-70% stenosis of the origin of the left internal carotid artery. A right carotid endarterectomy was performed on 17APR00. A biopsy showed fibroatheromatous plaque (right carotid). He was discharged from the hospital on 19APR00. The patient recovered from being hypotensive, but otherwise his clinical outcome is unknown.

Additional information was received from an attorney on 18JAN01 in the form of medical records from an orthopedic surgeon indicating the patient had a history of cellulitis/diabetic ulcer with an infection beginning on 01OCT91.

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B.6 Relevant tests/laboratory data, including dates (Cont...)

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the following: "Moderate 60-79% stenosis proximal right internal carotid artery."
10SEP97 Abdominal ultrasound (US): revealed bilateral renal parenchymal cysts, a mildly prominent spleen, and no evidence of cholelithiasis or ductal dilation
10SEP97 Pelvic US: prostatic hypertrophy
10SEP97 Chest and abdominal X-ray revealed nonspecific dilation of a redundant loop of the sigmoid colon, no evidence of obstruction and no acute chest pathology

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11SEP97 Computed tomography (CT) of the abdomen and pelvis revealed left renal cyst, diffusely atrophic pancreas, no evidence of hepatosplenomegaly, no discrete abnormalities of the liver, no dilation of the biliary tree, and no intra-abdominal masses
 11SEP97 Echocardiogram (ECHO) was normal other than a non-dilated left ventricle with concentric left ventricular hypertrophy and normal systolic function and minimal mitral annular calcification
 11SEP97 Urinalysis: 1+ glucose, bilirubin positive, few bacteria, and moderate crystals
 12SEP97 Holter monitor (20 hours): rare isolated atrial premature beats, frequent isolated ventricular extrasystoles with rare couplets, no significant pauses, no ischemia, no symptoms
 18SEP97 Liver biopsy revealed "pronounced subacute hepatitis including hydropic degeneration, acidophilic bodies, lymphoplasmacytic infiltrate within the lobules and portal tract as well as areas of bridging necrosis. Occasional eosinophils present within the inflammatory infiltrate and sinusoids. The histologic appearance is variable and could be consistent with drug etiology. However, acute viral hepatitis cannot be excluded on histologic basis alone."
 05DEC97 Stool for guaiac: negative, urea nitrogen/creatinine ratio: 39 (7-29)
 06DEC97 Esophagogastroduodenoscopy (EGD) revealed diffuse gastritis with erosions, distal esophageal ulcer with surrounding Mallory Weiss tears, diffuse duodenitis, sliding hiatus hernia and esophageal motility disorder
 07DEC97 Helicobacter pylori: IGG - positive, IGM - negative, IGA - positive, Index - 0.54 (negative <0.74)
 08DEC97 Abdominal US: fatty liver, splenomegaly, ascites
 25MAR98 Mitochondrial antibodies of <1:20 (<1:20 negative)
 09SEP98 EGD: showed massive upper GI bleeding secondary to esophageal varices, likely caused by liver cirrhosis and portal hypertension.
 18SEP98 Abdominal ultrasound revealed evidence of cirrhosis with splenomegaly, normal hepatopetal portal blood flow, moderate ascites, and poorly visualized hepatic veins likely due to cirrhosis
 22SEP98 EGD: revealed distal esophageal varices, portal hypertensive gastropathy, and antral gastritis with polypoid appearing mucosa
 22SEP98 Biopsies of the gastric antrum: showed moderate chronic active gastritis with no metaplasia or dysplasia, and no definite helicobacter pylori
 13OCT98 EGD with vericeal band ligation
 01DEC98 EGD, saline assisted polypectomy, snare polypectomy: antral polypoid lesions; portal hypertensive gastropathy; distal esophageal varices, Grade I to II with no evidence of active or recent hemorrhage; sliding hiatal hernia
 01FEB99 EGD/Variceal band ligation revealed distal esophageal varices and successful band ligation x two with no signs of residual varices, and portal hypertensive gastropathy.
 27AUG99 EGD/gastric polypectomy revealed gastric antral polyps that were snare excised, portal hypertensive gastropathy, status/post variceal band ligation for esophageal varices with no evidence of active varices
 22NOV99 Colonoscopy with polypectomy revealed splenic flexure and sigmoid colon polyps (excised), redundant tortuous colon secondary to chronic constipation and underlying motility disorder from diabetes, and internal hemorrhoids
 05APR00 Nuclear stress test: normal myocardial perfusion
 17APR00 Doppler: 90% right carotid stenosis, 60-70% stenosis of the origin of the left internal carotid artery
 17APR00 Biopsy right carotid artery: fibroatheromatous plaque
 12JUN00 Colonoscopy revealed colonic polyps (excised and sent for pathology), right sided portal hypertensive colopathy and prominent erythematous ileocecal valve, redundant colon, and large internal hemorrhoids with prominent rectal veins
 12JUN00 EGD: status post esophageal variceal band ligation with no evidence of recurrent varices. Diffuse gastritis with antral predominance, consistent with portal hypertensive gastropathy. Large antral and pre-pyloric polypoid lesions (hyperplastic on prior pathology). Incompetent lower esophageal sphincter

Lab Result :

Sl.No.	Test name	Test date	Test result	Normal value
1	ALANINE AMINOTRANSFERASE	02/06/97	26 U/L	1-65
		08/26/97		
		09/10/97	1082 IU/L	1-44
		09/11/97	1465 U/L	2-50
		09/12/97	1496	
		09/13/97	1505 U/L	2-50
		09/13/97	1516 U/L	2-50
		09/14/97	1588 U/L	2-50
		09/15/97	1437 U/L	2-50
		09/16/97	1530 U/L	2-50
		09/17/97	1385 U/L	2-50
		09/18/97	1437 U/L	2-50
		09/19/97	1417 U/L	2-50
		09/20/97	1417 U/L	2-50
		09/25/97	940 IU/L	1-44
		10/02/97	562 IU/L	1-44
		10/09/97	399 IU/L	1-44

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		10/16/97	305 IU/L	1-44
		10/23/97	274 IU/L	1-44
		11/06/97	165 IU/L	1-44
		11/20/97	111 IU/L	1-44
		12/07/97	104 U/L	2-50
		12/26/97	79 U/L	1-44
		01/07/98	58 U/L	1-44
		01/28/98	47 U/L	1-44
		02/25/98	65 U/L	5-40
		03/25/98	68 U/L	7-56
		05/14/98	35 U/L	0-50
		09/09/98	56 U/L	30-65
		09/10/98	47 U/L	30-65
		11/09/98	22 IU/L	5-40
2	ALBUMIN	09/20/97	3.2 gm/dL	3.0-5.2
		11/06/97	3.3 gm/dL	3.6-4.6
		12/05/97	2.4	
		12/26/97	3.4 gm/dL	3.6-4.6
		01/07/98	3.5 gm/dL	3.6-4.6
		01/28/98	3.5 gm/dL	3.6-4.6
		02/25/98	3.4 gm/dL	3.7-4.7
		09/08/98	2.6	
		09/10/98	2.4 gm/dL	3.4-4.8
		11/09/98	3.7 gm/dL	3.7-4.7
		12/05/97	0.8	1.0-2.2
3	ALBUMIN/GLO- BULIN RATIO			
4	ALKALINE PHOSPHATASE	08/02/96	69 U/L	30-125
		02/06/97	71 U/L	20-125
		08/26/97	84 U/L	30-140
		09/10/97	113 U/L	30-125
		09/11/97	120	
		09/12/97	121 U/L	30-125
		09/13/97	116 U/L	30-125
		09/14/97	124 U/L	30-125
		09/15/97	123 U/L	30-125
		09/16/97	127 U/L	30-125
		09/17/97	127 U/L	30-125
		09/18/97	129 U/L	30-125
		09/19/97	134 U/L	30-125
		09/20/97	134 U/L	30-125
		09/25/97	135 U/L	30-134
		10/02/97	128 U/L	30-140
		10/09/97	151 U/L	30-140
		10/16/97	181 U/L	30-140
		10/23/97	210 U/L	30-140
		11/06/97	228 U/L	30-140
		11/20/97	295 U/L	30-140
		12/07/97	300 U/L	30-125
		12/26/97	628 U/L	30-140
		01/07/98	485 U/L	30-140
		01/28/98	331 U/L	30-140
		02/25/98	357 U/L	30-110
		03/25/98	313 U/L	38-126
		09/08/98	226	
		09/09/98	226 U/L	50-155
		09/10/98	158 U/L	50-155
		11/09/98	189 U/L	30-130
		06/02/99	182 IU/L	25-160
		11/09/98	1.70 IU/ML	0-9.1
5	ALPHA 1 FETOPROTEIN			
6	ANTI SMOOTH MUSCLE ANTIBODY	09/25/97	40	<20
7	ANTI-DNA ANTIBODY	09/25/97	<10	<10
8	ANTI-HISTONE ANTIBODY	09/25/97	POSITIVE	
9	ANTIMITOCHO- NDRIAL ANTIBODY	03/25/98	<1:20	<1:20
10	ANTINUCLEAR ANTIBODY	09/11/97	NON-REACTIVE	
11	ASPARTATE AMINOTRANSF- ERASE	03/25/98	1:80	<1:40
		08/02/96	14 U/L	1-45
		02/06/97	29 U/L	1-50
		08/26/97	463 IU/L	1-45
		09/10/97	803 U/L	7-45
		09/11/97	860	
		09/12/97	790 U/L	7-45
		09/13/97	889 U/L	7-45
		09/14/97	981 U/L	7-45
		09/15/97	905 U/L	7-45
		09/16/97	907 U/L	7-45
		09/17/97	775 U/L	7-45
		09/18/97	820 U/L	7-45
		09/19/97	773 U/L	7-45
		09/20/97	775 U/L	7-45
		09/25/97	604 IU/L	1-45
		10/02/97	349 IU/L	1-45
		10/09/97	274 IU/L	1-45
		10/16/97	209 IU/L	1-45

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		10/23/97	203 IU/L	1-45
		11/06/97	117 IU/L	1-45
		11/20/97	93 IU/L	1-45
		12/07/97	99 U/L	7-45
		12/26/97	86 U/L	1-45
		01/07/98	53 U/L	1-45
		01/28/98	46 U/L	1-45
		02/25/98	60 U/L	5-35
		03/25/98	56 U/L	15-46
		05/14/98	42 U/L	0-40
		09/09/98	35 U/L	15-37
		09/10/98	33 U/L	15-37
		11/09/98	28 IU/L	5-35
12	BIOPSY	09/18/97	SEE LAB TEXT	
		09/22/98	SEE LAB TEXT	
		04/17/00	SEE LAB TEXT	
		RIGHT CAROTID ARTERY		
13	BLOOD PRESSURE	09/08/98	80 SYSTOLIC	
		09/08/98	105 SYSTOLIC	
		AFTER INTRAVENOUS FLUID THERAPY		
		04/17/00	180/90	
14	CALCIUM	09/20/97	8.9 mg/dL	8.5-10.5
15	CARBON DIOXIDE	09/20/97	25 mEq/L	20-30
16	CHEST X-RAY	08/26/97	SEE LAB TEXT	
		09/10/97	SEE LAB TEXT	
		04/11/00	MILD CARDIOMEGLY	
17	CHLORIDE	09/20/97	103 mEq/L	96-109
18	CHOLESTEROL	09/12/97	147	170-275
		09/20/97	167	170-275
		04/10/00	203	100-199
19	COLONOSCOPY	11/22/99	SEE LAB TEXT	
20	CREATININE	08/02/96	1.1 mg/dL	0.5-1.4
		08/26/97	1.40 mg/dL	0.60-1.20
		09/20/97	1.1 mg/dL	0.5-1.3
		12/26/97	1.3 mg/dL	0.6-1.2
		01/07/98	1.4 mg/dL	0.6-1.2
		03/25/98	1.2 mg/dL	0.6-1.5
		09/10/98	0.9 mg/dL	0.8-1.3
21	CREATININE CLEARANCE	09/16/97	3360 mg/24 hr	1000-1900
		09/16/97	212 ML/MIN	107-139
22	CT SCAN	09/11/97	SEE LAB TEXT	
23	CYTOMEGALOVIRUS	09/25/97	2.91 (POSITIVE; IGG)	0-0.9
		09/25/97	0.68 (NEGATIVE; IGM)	0-0.89
24	DIRECT BILIRUBIN	02/06/97	0.3 mg/dL	0-0.4
		08/26/97	0.86 mg/dL	0-0.2
		09/10/97	3.8 mg/dL	0-0.2
		09/25/97	6.55 mg/dL	0-0.2
		10/02/97	6.02 mg/dL	0-0.2
		10/09/97	5.4 mg/dL	0-0.2
		10/16/97	5.52 mg/dL	0-0.2
		10/23/97	4.71 mg/dL	0-0.2
		11/06/97	1.99 mg/dL	0-0.2
		11/20/97	1.75 mg/dL	0-0.2
		12/05/97	3.1 mg/dL	0-0.2
		01/28/98	0.63 mg/dL	0-0.2
		09/09/98	0.39 mg/dL	0-0.3
		09/10/98	0.42 mg/dL	0.00-0.30
25	DOPPLER STUDY	08/28/97	SEE LAB TEXT	
		04/19/00	SEE LAB TEXT	
26	ECHOCARDIOGRAM	09/11/97	SEE LAB TEXT	
		09/11/97	SEE LAB TEXT	
27	ELECTROCARDIOGRAM	08/27/97	SEE LAB TEXT	
28	EPSTEIN-BARR VIRUS	09/25/97	409 (POSITIVE)	0-100
29	ERYTHROCYTE SEDIMENTATION RATE	09/10/97	25 mm/hr	0-10
30	ESOPHAGOGASTRODUODENOSCOPY	12/06/97	SEE LAB TEXT	
		09/22/98	SEE LAB TEXT	
		10/13/98	SEE LAB TEXT	
		12/01/98	SEE LAB TEXT	
		02/01/99	SEE LAB TEXT	
		08/27/99	SEE LAB TEXT	
31	FASTING GLUCOSE	01/07/98	350.0 mg/dL	65.0-115
32	FERRITIN	08/26/97	2104 mcg/L	10-107
		09/12/97	2166 ng/mL	18-440
		09/25/97	1629 mcg/L	23-233
33	GAMMA GLUTAMYL TRANSPEPTIDASE	02/06/97	26 U/L	1-65

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		08/26/97	257 U/L	1-78
		09/25/97	615 U/L	1-109
		10/02/97	649 U/L	1-78
		10/09/97	833 U/L	1-78
		10/16/97	886 U/L	1-78
		10/23/97	1158 U/L	1-78
		11/06/97	1040 U/L	1-78
		11/20/97	1160 U/L	1-78
		12/26/97	1002 U/L	1-78
		01/07/98	691 U/L	1-78
		01/28/98	346 U/L	1-78
		02/25/98	312 U/L	5-60
		03/25/98	272 U/L	8-78
		05/14/98	149 U/L	0-65
		11/09/98	128 U/L	5-60
		06/02/99	153 IU/L	0-85
		03/07/00	108 IU/L	0-85
34	GLOBULIN	09/20/97	3.5 gm/dL	2.0-4.5
		11/09/98	4.1 gm/dL	2.2-3.8
35	GLUCOSE	02/05/97	292 mg/dL	
		08/26/97	444 mg/dL	65-115
		09/13/97	124 mg/dL	84-127
		09/19/97	221 mg/dL	84-127
		12/05/97	501 mg/dL	
		09/08/98	355	
		04/19/00	201	
36	HEMATOCRIT	09/10/97	40.8 %	42-52
		12/06/97	31.0	
		09/17/98	27.3 %	37.5-49.0
		11/09/98	28.0 Percent	34.0-47.0
		03/27/00	31.5 %	36-50
37	HEMOGLOBIN	09/11/97	14	
		12/06/97	10.6	
		09/08/98	10.6	
		09/17/98	9.60 g/dL	12.8-16.9
		11/09/98	9.50 gm/dL	11.6-15.0
		03/27/00	10.0 g/dL	12.5-17
38	HEPATITIS A ANTIBODY	09/12/97	NEGATIVE	
39	HEPATITIS B ANTIGEN	09/25/97	NEGATIVE	
		09/18/97	NEGATIVE	
40	HEPATITIS C ANTIGEN	09/18/97	NEGATIVE	
41	HOLTER MONITOR	09/12/97	SEE LAB TEXT	
42	INTERNATIONAL NORMALIZED RATIO	01/09/97	1.2	
43	IRON	04/10/00	1.2	2.0-3.5
44	LACTATE DEHYDROGENASE	08/26/97	181 mcg/L	45-145
		08/02/96	173 U/L	100-225
		02/06/97	217 U/L	50-250
		08/26/97	392 IU/L	95-234
		09/10/97	1021 U/L	313-618
		09/12/97	988 U/L	313-618
		09/13/97	1183 U/L	313-618
		09/14/97	1231 U/L	313-618
		09/16/97	1099 U/L	313-618
		09/17/97	1028 U/L	313-618
		09/18/97	1035 U/L	313-618
		09/19/97	969 U/L	313-618
		09/20/97	969 U/L	313-618
		09/25/97	278 IU/L	95-234
		10/02/97	213 IU/L	95-234
		10/09/97	214 IU/L	95-234
		10/16/97	225 IU/L	95-234
		10/23/97	209 IU/L	95-234
		11/06/97	175 IU/L	96-234
		11/20/97	208 IU/L	95-234
		11/09/98	199 IU/L	100-230
45	LIVER FUNCTION TESTS	09/09/98	NORMAL	
46	LYME DISEASE SEROLOGY	06/02/99	1.65	0-0.89
		LYME DISEASE/LYME AB, TOTAL IMMUNOGLOBULIN/LYME EIA POSITIVE		
		06/23/99	1.81	0-0.89
		LYME EIA POSITIVE		
47	LYMPHOCYTE PERCENT	12/05/97	12 %	20-40%
48	MEAN CELL HEMOGLOBIN	03/27/00	24.3	27-34
49	MEAN CELL HEMOGLOBIN CONCENTRATION	03/27/00	31.7 g/dL	32-36
50	MEAN CELL VOLUME	09/22/98	95 fL	80-94
51	MEAN	03/27/00	77 fL	80-98
		12/05/97	11.6 fL	7.4-10.4

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52	PLATELET VOLUME	09/20/97	3.5 mg/dL	2.5-5.0
53	PHOSPHORUS	08/26/97	146.0 x10 ³ /mm ³	150-400
54	PLATELET COUNT	11/09/98	204 x10 ³ /mm ³	150-400
		09/12/97	4.6	
		09/16/97	5.7	3.3-5.3
		09/18/97	5.7 mmol/L	3.3-5.3
		09/20/97	4.9 mmol/L	3.3-5.3
55	PROTHROMBIN TIME	01/09/97	14.0	
		09/13/97	13.8	
		12/26/97	12.7 seconds	10.9-13.3
		01/07/98	12.2 seconds	10.9-13.3
56	RED BLOOD CELL COUNT	09/10/97	4.36 x10 ⁶ /mm ³	4.70-6.10
		09/17/98	2.94 x10 ⁶ /mm ³	4.00-5.60
		11/09/98	3.36 x10 ⁶ /mm ³	3.80-5.22
57	SODIUM	09/12/97	138 mEq/L	133-145
		09/13/97	140	133-145
		01/07/98	132.0 mmol/L	134-145
58	THYROID STIMULATING HORMONE	02/05/97	9.30	0.4-6.2
		04/09/97	5.64	0.49-4.7
		03/07/00	11.56 mcU/mL	0.35-5.50
59	TOTAL BILIRUBIN	08/02/96	0.5 mg/dL	0.1-1.5
		02/06/97	0.6 mg/dL	0-1.2
		08/26/97	2.03 mg/dL	0.2-1.1
		09/10/97	5.6 mg/dL	0.2-1.2
		09/11/97	5.9 mg/dL	0.2-1.2
		09/12/97	6.2 mg/dL	0.2-1.2
		09/13/97	6.0 mg/dL	0.2-1.2
		09/14/97	6.6 mg/dL	0.2-1.2
		09/15/97	6.5 mg/dL	0.2-1.2
		09/16/97	6.7 mg/dL	0.2-1.2
		09/17/97	6.6 mg/dL	0.2-1.2
		09/18/97	7.2 mg/dL	0.2-1.2
		09/19/97	7.8 mg/dL	0.2-1.2
		09/20/97	7.8 mg/dL	0.2-1.2
		09/25/97	13.2 mg/dL	0.3-1.4
		10/02/97	11.6 mg/dL	0.2-1.1
		10/09/97	10.3 mg/dL	0.2-1.1
		10/16/97	11.7 mg/dL	0.2-1.1
		10/23/97	10.1 mg/dL	0.2-1.1
		11/06/97	7.25 mg/dL	0.2-1.1
		11/20/97	6.67 mg/dL	0.2-1.1
		12/05/97	5.3 mg/dL	0.2-1.2
		12/26/97	6.5 mg/dL	0.2-1.1
		01/07/98	4.32 mg/dL	0.2-1.1
		01/28/98	2.51 mg/dL	0.2-1.1
		01/28/98	1.88 mg/dL	0.2-1.3
		02/25/98	1.73 mg/dL	0.2-1.1
		03/25/98	1.3 mg/dL	0.2-1.3
		05/14/98	1.6 mg/dL	0.1-1.2
		09/09/98	0.8 mg/dL	0-1.2
		09/10/98	0.9 mg/dL	0-1.2
		11/09/98	0.81 mg/dL	0.2-1.1
60	TOTAL PROTEIN	09/12/97	7.0 g/dL	6.0-8.1
		09/20/97	6.7 g/dL	6.0-8.1
61	TRIGLYCERIDES	02/05/97	234 mg/dL	
		09/12/97	219	
		09/20/97	196 mg/dL	<175
62	ULTRASOUND	08/27/97	SEE LAB TEXT	
	ABDOMEN AND PELVIS	09/10/97	SEE LAB TEXT	
	ABDOMINAL	12/08/97	SEE LAB TEXT	
		09/18/98	SEE LAB TEXT	
63	UREA NITROGEN	08/02/96	23 mg/dL	8-28
		09/20/97	19 mg/dL	5-21
		12/05/97	47 mg/dL	5-21
		12/26/97	24 mg/dL	9-27
		01/07/98	23 mg/dL	9-27
		03/25/98	16 mg/dL	8-24
		09/10/98	27 mg/dL	6-28
64	URIC ACID	09/20/97	4.9 mg/dL	2.5-7.5
65	URINALYSIS	09/11/97	SEE LAB TEXT	
66	WEIGHT	12/06/97	230 lbs	
		04/13/00	229 lbs	
67	X-RAY	09/10/97	SEE LAB TEXT	

B.7 Other relevant history, including preexisting medical conditions (Cont...)

Autonomic neuropathy
 Legally blind with diabetic retinopathy
 Hypothyroidism
 Foot ulcer

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Impotence
Multiple diabetic complications
"Severe underlying liver problems prior to Rezulin (troglitazone)"
Carotid stenosis
Hypertension
Peripheral vascular disease
Elevated cholesterol
Bilateral lower extremity claudication
Varicose vein surgery
Hiatal hernia
Anemia
Thyroid nodule
Hashimoto's Thyroiditis
Fractured right tibia and patella
Poorly controlled diabetes
Hyperlipidemia
Left sided empyema as a child with drainage
01OCT91 Cellulitis/diabetic ulcer with infection of the left foot
21JAN93 arthritis
13MAY93 artherosclerosis
13JAN94 "white outs"
31JAN94 cellulitis
08FEB94 left foot infection

C. Suspect medication (Cont...)

Seq No. : 1
C.1 Suspect medication : REZULIN 400MG TABLET(TROGLITAZONE)
C.2 Dose, frequency & route used : 2) 400 mg (Daily), Per oral
C.3 Therapy Dates (or duration) : 2) 05/21/97 - 09/11/97

C10. Concomitant medical products

Seq No. : 2
Concomitant Medical Product : HUMULIN 70/30 (INSULIN HUMAN INJECTION, ISOPHANE, INSULIN HUMAN ZINC SUSPENSION)
Therapy Dates : 1) Unk - Ongoing

Seq No. : 3
Concomitant Medical Product : SYNTHROID (LEVOTHYROXINE SODIUM)
Therapy Dates : 1) Unk - Ongoing

Seq No. : 4
Concomitant Medical Product : GLYNASE (GLIBENCLAMIDE)
Therapy Duration : Unk

Seq No. : 5
Concomitant Medical Product : MONOPRIL (FOSINOPRIL SODIUM)
Therapy Duration : Unk

Seq No. : 6
Concomitant Medical Product : LIPITOR (ATORVASTATIN)
Therapy Duration : Unk
Approval information :
NDA # : 20-702

Seq No. : 7
Concomitant Medical Product : REGLAN (METOCLOPRAMIDE)
Therapy Duration : UNK

Seq No. : 8
Concomitant Medical Product : PRILOSEC (OMEPRAZOLE)
Therapy Duration : Unk

Seq No. : 9
Concomitant Medical Product : (FOLIC ACID)
Therapy Duration : Unk

Seq No. : 10
Concomitant Medical Product : VITAMIN E (TOCOPHEROL)
Therapy Duration : Unk

Seq No. : 11
Concomitant Medical Product : GLYBURIDE (GLIBENCLAMIDE)

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Therapy Dates	: 1) Unk - 09/12/97
Seq No.	: 12
Concomitant Medical Product	: VITAMIN A (RETINOL)
Therapy Duration	: Unk
Seq No.	: 13
Concomitant Medical Product	: VITAMIN B
Therapy Duration	: Unk
Seq No.	: 14
Concomitant Medical Product	: VITAMIN C (ASCORBIC ACID)
Therapy Duration	: Unk
Seq No.	: 15
Concomitant Medical Product	: ALDACTONE (SPIRONOLACTONE)
Therapy Duration	: Unk
Seq No.	: 16
Concomitant Medical Product	: CARAFATE (SUCRALFATE)
Therapy Duration	: Unk

G. All manufacturers

8. Adverse event term(s)

- 7) PORTAL HYPERTENSIVE GASTROPATHY
- 8) ASCITES
- 9) POSITIVE EPSTEIN-BARR VIRUS
- 10) GASTRITIS
- 11) ARTERIAL OCCLUSION
- 12) DUODENITIS
- 13) ESOPHAGEAL ULCER
- 14) HEMATEMESIS
- 15) HYPOTENSIVE
- 16) DRUG INDUCED FULMINANT HEPATITIS
- 17) LIVER FAILURE
- 18) LIVER NECROSIS
- 19) JAUNDICE
- 20) NOT FEELING WELL
- 21) COLON POLYPS
- 22) POSITIVE ANTI-HISTONE ANTIBODY
- 23) ELEVATED SERUM FERRITIN
- 24) POSITIVE ANA
- 25) LEFT KIDNEY CYST
- 26) ENLARGED PROSTATE
- 27) POSITIVE ANTI-SMOOTH MUSCLE ANTIBODIES
- 28) PALPITATIONS
- 29) COLOPATHY
- 30) INCOMPETENT LOWER ESOPHAGEAL SPHINCTER
- 31) TORTUOUS COLON
- 32) CHRONIC CONSTIPATION
- 33) GASTROPATHY
- 34) SHORTNESS OF BREATH
- 35) SWEATY
- 36) BELCHING
- 37) DECREASED INR
- 38) LYME DISEASE
- 39) HEMORRHOIDS
- 40) SPLENOMEGALY
- 41) HYPERPLASTIC POLYP
- 42) GYNECOMASTIA
- 43) MALLORY WEISS TEAR
- 44) ESOPHAGEAL MOTILITY DISORDER
- 45) RECTAL BLEEDING
- 46) TUBULAR ADENOMA
- 47) HYPOALBUMINEMIA
- 48) ATROPHIC PANCREAS
- 49) ELEVATED GLUCOSE
- 50) LIGHTHEADEDNESS
- 51) WORSENING OF CAROTID STENOSIS
- 52) CARDIOMEGALY
- 53) OFF LABEL USE

DSS

JAN 31 2001

JAN 30 2001



REGULATORY SAFETY
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 07/25/95

Mfr report #	001-0981-M0100514
UF Dist report #	
FDA Use On	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 5

A. Patient Information

1. Patient identifier	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 170 lbs or _____ kgs
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B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply): <input type="checkbox"/> death: _____ (m/d/yy) <input type="checkbox"/> life-threatening <input checked="" type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____	
3. Date of event (m/d/yy): UNK	4. Date of this report (m/d/yy): 01/29/01

5. Describe event or problem

This is a report from [redacted] a patient support program by which a patient request information on a specific disease state. This consumer on Lipitor (atorvastatin) 20mg per day to "lower cholesterol" since 01APR00 has experienced "stomach ulcers", "high blood pressure" and "some irregular heart rhythms". He was hospitalized for an unknown reason at an unknown time. He is currently taking Baby aspirin, Zantac (ranitidine), Folic Acid, Vitamin B, Accupril (quinapril), Lanoxin (digoxin), Flovent (fluticasone propionate), and Combivent (ipratropium bromide and albuterol sulfate). It is uncertain if the events occurred before or after the intake of Lipitor.

6. Relevant tests/laboratory data, including dates
Unknown Date: Blood Pressure "90/115"

Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

-Blood Type (present): A+

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1	ATORVASTATIN (ATORVASTATIN)
#2	(ACETYLSALICYLIC ACID)
2. Dose, frequency & route used	
#1	20 mg
#2	81 mg (DAILY)
3. Therapy dates (if unknown, give duration: from/to (or best estimate))	
#1	04/01/00 - Unknown
#2	Unknown - Unknown
4. Diagnosis for use (indication)	
#1	HIGH CHOLESTEROL
#2	UNKNOWN
5. Event abated after use stopped or dose reduced	
#1	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply Unk
#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply Unk
6. Lot # (if known)	
#1	
#2	
7. Exp. date (if known)	
#1	
#2	
8. Event reappeared after reintroduction	
#1	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply Unk
#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply Unk
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event):	
1) UNK	

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)	2. Phone number
PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42ND STREET NEW YORK NY 10017 USA (Initial Unit)	(212) 573-3129
4. Date received by manufacturer (m/d/yy)	5. (A)NDA #
10/12/00	20-702
6. If IND, protocol #	IND #
	PLA #
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic	
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____	
9. Mfr. report number	8. Adverse event term(s)
001-0981-M0100514	1) REACTION UNEVALUABLE 2) STOMACH ULCER 3) HIGH BLOOD PRESSURE 4) IRREGULAR HEART RHYTHM
3. Report source (check all that apply)	
<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other: _____	

E. Initial reporter

1. Name, address & phone #
[redacted] USA

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation Unknown	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk
--	--------------------------	---

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



REGULATORY SAFETY
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 09/25/95

Mfr report #
001-0981-M0100514

US/Dev report #

FDA FORM 1085

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 2 of 5

A. Patient Information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g. defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#3 (RANITIDINE)

#4 (FOLIC ACID)

2. Dose, frequency & route used

#3 (Unknown)

#4 (Unknown)

3. Therapy dates (if unknown, give duration - from/to for best estimate)

#3 Unknown - Unknown

#4 Unknown - Unknown

4. Diagnosis for use (indication)

#3 UNKNOWN

#4 UNKNOWN

5. Event abated after use stopped or dose reduced

#3 yes no doesn't apply
Unk

#4 yes no doesn't apply
Unk

6. Lot # (if known)

#3

#4

7. Exp. date (if known)

#3

#4

8. Event reappeared after reintroduction

#3 yes no doesn't apply
Unk

#4 yes no doesn't apply
Unk

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

2. Phone number

3. Report source (check all that apply)

foreign

study

literature

consumer

health professional

user facility

company representative

distributor

other: _____

4. Date received by manufacturer (mo/day/yr)

5. (A)NDA # _____

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

6. If IND, protocol #

7. Type of report (check all that apply)

5-day 15-day

10-day periodic

Initial follow-up # _____

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name, address & phone #

2. Health professional?
 yes no

3. Occupation

4. Initial reporter also sent report to FDA
 yes no unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



LABORATORY SAFETY
 or use by user-facilities,
 distributors and manufacturers for
 MANDATORY reporting

Approved by FDA on 9/25/95

Mfr report # 001-0981-M0100514
UF/Dist report #
FDA Use Only

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 3 of 5

A. Patient Information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply): <input type="checkbox"/> death (mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other: _____	
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests-laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #5 VITAMIN B #6 (QUINAPRIL HYDROCHLORIDE)		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #5 Unknown - Unknown #6 Unknown - Unknown	
2. Dose, frequency & route used #5 (Unknown) #6 (Unknown)		5. Event abated after use stopped or dose reduced #5 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #6 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
4. Diagnosis for use (indication): #5 UNKNOWN #6 UNKNOWN		8. Event reappeared after reintroduction #5 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #6 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known) #5 #6	7. Exp. date (if known) #5 #6	9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)			

G. All manufacturers

1. Contact office - name/address (& mfg site for devices)		2. Phone number
4. Date received by manufacturer (mo/day/yr)		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other: _____
6. If IND, protocol #		
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		
9. Mfr. report number		
5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes		8. Adverse event term(s)

E. Initial reporter

1. Name, address & phone #		
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FEB 1 2001



LATORY SAFETY
or use by user-facilities,
tors and manufacturers for
MANDATORY reporting

Approved by FDA on 09/25/95

Mfr report #	001-0981-M0100514
UF/Dist report #	
FDA I Form #	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 4 of 5

A. Patient information

1. Patient identifier	2. Age at time of event: or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
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B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death _____ (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration from to (or best estimate))	
#7 (DIGOXIN)		#7 Unknown - Unknown	
#8 (FLUTICASONE PROPIONATE)		#8 Unknown - Unknown	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#7 0.125 mg (DAILY)		#7 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does n't appl.	
#8 (Unknown)		Unk	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#7 UNKNOWN		#7 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does n't appl.	
#8 UNKNOWN		Unk	
6. Lot # (if known)	7. Exp. date (if known)	9. NDC # - for product problems only (if known)	
#7	#7		
#8	#8		
10. Concomitant medical products and therapy dates (exclude treatment of event)			

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)		2. Phone number	
4. Date received by manufacturer (mo/day/yr)		5. (A)NDA # _____	
6. If IND, protocol #		IND # _____	
7. Type of report (check all that apply)		PLA # _____	
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day		pre-1938 <input type="checkbox"/> yes	
<input type="checkbox"/> 10-day <input type="checkbox"/> periodic		OTC product <input type="checkbox"/> yes	
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		8. Adverse event terms	
9. Mfr. report number		Report source (check all that apply)	
		<input type="checkbox"/> foreign	
		<input type="checkbox"/> study	
		<input type="checkbox"/> literature	
		<input type="checkbox"/> consumer	
		<input type="checkbox"/> health professional	
		<input type="checkbox"/> user facility	
		<input type="checkbox"/> company representative	
		<input type="checkbox"/> distributor	
		<input type="checkbox"/> other: _____	

E. Initial reporter

1. Name, address & phone #		
DOB FFB 02 2001		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



MANDATORY SAFETY REPORT
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 09/25/04

Mfr report #	001-C981-M0100514
UF/Dist report #	
FDA Use Only	

FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 5 of 5

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or Date of birth:	3. Sex <input type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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B. Adverse event or product problem

1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	
3. Date of event (mo/day/yr)	4. Date of this report (mo/day/yr)

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #9 (IPRATROPIUM BROMIDE, SALBUTAMOL SULFATE) #10	
2. Dose, frequency & route used #9 (Unknown) #10	3. Therapy dates (if unknown, give duration from/to (or best estimate)) #9 Unknown - Unknown #10
4. Diagnosis for use (indication) #9 UNKNOWN #10	5. Event abated after use stopped or dose reduced #9 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply Unk #10 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply
6. Lot # (if known) #9 #10	7. Exp. date (if known) #9 #10
8. Event reappeared after reintroduction #9 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply Unk #10 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

G. All manufacturers

1. Contact office - name/address (& mfrng site for devices)		2. Phone number
4. Date received by manufacturer (mo/day/yr)		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:
6. If IND, protocol #		
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input type="checkbox"/> Initial <input type="checkbox"/> follow-up # _____		
5. (A)NDA # _____ IND # _____ PLA # _____ pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes		8. Adverse event term(s)
9. Mfr. report number		

E. Initial reporter

1. Name, address & phone #		
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FEB 02 2005
FEB 1 2005

Individual Safety Report



3660339-4-00-01

or VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only

Triage unit sequence # 136889

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

A. Patient information

1. Patient identifier:
In confidence

2. Age at time of event:
or
Date of birth:

3. Sex: female male

4. Weight: 182 lbs or kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other

3. Date of event: 10/03/2000

4. Date of this report: 11/28/2000

5. Describe event or problem:
 Pt. admitted to hx. of black tarry stool and hematemesis. On 10/4/00, pt. had ↓ Hemoglobin / Hematocrit and felt nauseous and became tachycardic. Pt. underwent cauterization and injection therapy of the ulcer. Pt. had blood transfusion because of the ↓ H+H.

6. Relevant tests/laboratory data, including dates:
 Telemetry
 Endoscopy
 10/6/00: HGB = 7.5 / HCT = 21.9
 10/8/00: HGB = 8.7 / HCT = 25.8

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 PCN Allergy

CTU136889

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler if known):
 #1 Aspirin
 #2

2. Dose, frequency & route used:
 #1 unknown, PO
 #2

3. Therapy dates (if unknown, give duration) from to (or best estimate):
 #1 For 1 week PTA
 #2

4. Diagnosis for use (indication):
 #1 unknown
 #2

5. Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known): #1 unknown #2

7. Exp. date (if known): #1 unknown #2

8. Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only):
 #1 #2

10. Concomitant medical products and therapy dates (exclude treatment of event):

D. Suspect medical device

1. Brand name:

2. Type of device:

3. Manufacturer name & address:

4. Operator of device:
 health professional
 lay user/patient
 other

5. Expiration date:

6. model #: MEDWATCH CTU
 catalog #: DSS
 serial #:
 lot #: FEB 05 2001
 other #:

7. If implanted, give date:

8. If explanted, give date:

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

1. Name, address & phone:
 Hospital
 Ave.

2. Health professional? yes no

3. Occupation: Pharmacist

4. Also reported to:
 manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

Individual Safety Report



3662247-1-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
health professionals of adverse
events and product problems

Internet Submission - Page 1

Form Approved: OME No. 0911-0291 Expires: 12/31/10
See CMI statement or revision

FDA Use Only

Triage unit
sequence #

137191

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event: or Date of birth: 66 Years	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------------	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event 11/20/2000 (mm/dd/yyyy)

4. Date of this report 02/07/2001 (mm/dd/yyyy)

5. Describe event or problem

Pt was transferred from LTC facility to med/surg facility due to c/o BRBPR and SOB.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

s/p resection of rectal CA



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of report does not constitute an admission that medical personnel or the product caused or contributed to the event.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler) #1 Aspirin / 325 mg /	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 09/18/2000 - 11/10/2000
2. Dose/Frequency/Route used #1 325 mg / daily / Oral	5. Event abated after use stopped or dose reduced? #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) #1	7. Exp. date (if known) #1
9. NDC # (for product problems only) -	
10. Concomitant medical products and therapy dates (exclude treatment of event) furosemide glyburide ISDN lisinopril metolazone KCl prednisone pramidone terazosin APAP diphenhydramine al	

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other

5. Expiration date (mm/dd/yyyy)

6. model # _____
catalog # MEDWATCH CTU
serial # _____
lot # _____
other # _____

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on _____

10. Concomitant medical products and therapy dates (exclude treatment of event)
FEB 08 2001

E. Reporter (see confidentiality section on back)

1. Name [Redacted] phone # [Redacted]

VA Pittsburgh Healthcare System - 132M-F-1, 7180 Highland Drive
Pittsburgh, Pennsylvania 15206
United States Mario.Dinardo@med.va.gov

2. Health professional?
 yes no

3. Occupation
Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.

MEDWATCH

CTV137191

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3662247-1-00-02

137191

MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 2 of 2

C10. Concomitant medical products and therapy dates continued

buterol reg insulin ipratropium

D10. Concomitant medical products and therapy dates continued

DSS

FEB 08 2001

137191

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



3662249-5-00-01

VOLUNTARY reporting
with professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/01
See OMB statement on "e-Reporting"

FDA Use Only

Tringe unit sequence # **137192**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1 of 2

A. Patient information

1. Patient identifier:

2. Age at time of event: **81 Years**
or Date of birth: _____

3. Sex: female male

4. Weight: _____ lbs or _____ kgs

In confidence

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (mm/dd/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: **11/22/2000** (mm/dd/yyyy)
 4. Date of this report: **02/07/2001** (mm/dd/yyyy)

5. Describe event or problem
 Patient was admitted from his nursing home after experiencing large heme positive emesis. Aspirin was discontinued and patient was treated with IV famotidine.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 dementia HTN CAD s/p MI COPD CHF UTI secondary to atonic bladder

MEDWATCH

CTU137192

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 Aspirin / 81 mg /
 #2 / /

2. Dose/Frequency/Route used
 #1 81 mg / daily / Oral
 #2 / /

3. Therapy dates (if unknown, give duration)
 #1 From - To (or best estimate)
 #2 - -

4. Diagnosis for use (separate indications with commas)
 #1 CAD
 #2

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)
 #1 #1
 #2 #2

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only)
 - -

10. Concomitant medical products and therapy dates (exclude treatment of event):
 digoxin felodipine prazosin
 lansoprazole lisinopril multivitamin
 thiamine APAP milk of mag
 Combivent FeSO4

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other:

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5. Expiration date (mm/dd/yyyy)

6. model # **FEB 08 2001**
 catalog # **MEDWATCH CTU**
 serial #
 lot #
 other #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA.)
 yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name phone:

DSS

VA Pittsburgh Healthcare System - 130M-HQ, 7180 Highways Drive
 Pittsburgh Pennsylvania
 United States Mario Dinard@med.va.gov **FEB 08 2001**

2. Health professional? yes no 3. Occupation Pharmacist 4. Also reported to
 manufacturer
 user/facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
 5600 Fishers Lane
 Rockville, MD 20852-9787
 or FAX to: 1-800-FDA-0178



3662249-5-00-02

MEDWATCH

137192

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5262

C10. Concomitant medical products and therapy dates continued

folic acid docusate

2

D10. Concomitant medical products and therapy dates continued

DSS

FEB 08 2001

137192

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



3662250-1-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/01
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **137193**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1 of 2

A. Patient information

1. Patient identifier: **[Redacted]**
In confidence

2. Age at time of event: **72 Years**
or Date of birth: _____

3. Sex: female male

4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/ malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (mm/dd/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: **11/26/2000** (mm/dd/yyyy)

4. Date of this report: **02/07/2001** (mm/dd/yyyy)

5. Describe event or problem:
 Pt was admitted after presentation to ER with c/o RLQ pain. Was admitted for work up of presumed lower GI bleed.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
CRI DM hypercholesterolemia HTN ED

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)
 #1 **EC ASA / 325 mg /**

2. Dose/Frequency/Route used
 #1 **325 mg / daily / Oral**

3. Therapy dates (if unknown, give duration)
 #1 From: - To: or best estimate: -

4. Diagnosis for use (separate indications with commas)
 #1 **prophylaxis**

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)
 #1 #1

8. Event reappeared after reintroduction
 #1 yes no doesn't apply

9. NDC # (for product problems only)
 - -

10. Concomitant medical products and therapy dates (exclude treatment of event)
APAP bisacodyl brimonidine clotrimazole cream diltiazem docosate glyburide pentoxifylline quinine ranitidin

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other:

5. Expiration date (mm/dd/yyyy)

6. model # **FEB 08 2001**

7. If implanted, give date (mm/dd/yyyy)

8. If exp. anted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on _____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name **[Redacted]** phone # **[Redacted]**

VA Pittsburgh Healthcare System - 132M-4 - 7.80 Highland Drive
 Pittsburgh Pennsylvania
 United States Mario.Dinardo@med.va.gov

2. Health professional? yes no 3. Occupation **Pharmacist**

4. As so reported to
 manufacturer
 user/facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH 5600 Fishers Lane, Rockville, MD 20852-1978
 or FAX to: 1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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CTU137193

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MEDWATCH CTU

DSS

FEB 08 2001

Individual Safety Report



3662250-1-00-02

MEDWATCH

137193

For VOLUNTARY reporting by health professionals of adverse events and product problems
Internet Submission - Page 5.2 of 2

C10. Concomitant medical products and therapy dates continued

e temazepam terazosin

D10. Concomitant medical products and therapy dates continued

DSS

FEB 08 2001

137193

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

Individual Safety Report



3662263-X-00-01

or VOLUNTARY reporting health professionals of adverse events and product problems

CDW

Form Approved: OMF No. (911-0291 Expires: 12-31-00 See UM3 statement on reverses)

FDA Use Only
Triage unit sequence # 137203

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient identifier: [redacted] In confidence
2. Age at time of event: 84 Years
or Date of birth: [redacted]
3. Sex: female male
4. Weight: 180 lbs or 82 kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (mm/dd/yyyy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: 12/28/2000 (mm/dd/yyyy)
4. Date of this report: 02/07/2001 (mm/dd/yyyy)

5. Describe event or problem
Patient presents to OBMT for a follow up of melena from ED a week before. Claims that signs/symptoms are better and has no abdominal pain. Diagnosed as UGI bleed.

6. Relevant tests/laboratory data, including dates
Rectal melena confirmed with heme positive. Hct 32.5, Hgb 10.8, INR 2.3, BP 159/66

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
HTN, CAD, A-fib, Dementia, CHF, PE, Hypothyroidism, RAD, BPH, Vit B12 deficiency.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr./Labeler)
 #1 Warfarin / 5mg /
 #2 Aspirin / 81mg /

2. Dose/Frequency/Route used
 #1 Variable / Use as directed / Oral
 #2 81mg / QD / Oral

3. Therapy dates (if unknown, give duration)
 #1 From - To (or best estimate)
 #2 -

4. Diagnosis for use (separate indications with commas)
 #1 A-fib, PE
 #2 CAD

5. Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known) #1 #2
 #1 #2

7. Exp. date (if known) #1 #2
 #1 #2

8. Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only)
 - -

10. Concomitant medical products and therapy dates (exclude treatment of event)
 Selenium sulfide, Psyllium, digoxin, levothyroxine, lisinopril, Vit B12 albutrol, acetaminophen, lansoprazole

D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device:
 health professional
 lay user/patient
 other

5. Expiration date (mm/dd/yyyy)
6. model #
7. If implanted, give date (mm/dd/yyyy)
8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] phone # [redacted]
 1055 Clermont St. DSS
 Denver Colorado 80220
 United States FEB 08 2001

2. Health professional? yes no
 3. Occupation Pharmacist
 4. Also reported to:
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.

Mail to: MEDWATCH or FAX to:
 5600 Fishers Lane 1-800-FDA-0178
 Rockville, MD 20852-9787



FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 137203 MEDWATCH

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FEB 08 2001

MEDWATCH CTU

Individual Safety Report



3662335-X-00-01

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nts and product problems

FDA Use only

137225

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier: 0023100297
 2. Age at time of event: 71
 3. Sex: female
 4. Weight: 165 lbs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event
 (Check all that apply)

death date: ___/___/___
 life threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event: 8/18/00
 4. Date of this report: 1/30/01

Description of event:
 10/1/69 GI bleed (nabumetone, ASA, clopidogrel) 71 year old female was admitted 8/18 with complaint of GI bleed. Hematocrit was 30 with INR 1.15. She had mild hematochezia, hematemesis with gross bleeding. Her stomach was full of blood. Past medical history includes hemorrhagic stroke and hypertension. Relafen, ASA, Plavix were discontinued. One consult states that she had been on warfarin since hospitalization in March for stroke. Further note on the stroke by neurology indicated that the mental status changes associated with the supposed stroke were correlated with the administration of Artane (for tremor) and that these mental status changes resolved when Artane discontinued. However, serial hematocrits were followed from 8/18-8/28. She had at least 2 more instances of gross GI bleed. 8/22 vomiting blood - Rx PRBC. 8/29 further GI bleed. She received multiple transfusions, octreotide, famotidine, lansoprazole and spent some time in ICU. The aspirin and warfarin were discontinued and antiplatelet therapy was recommended for the heart disease. There was no further bleeding. (possible 2)

DSS
FEB 09 2001

CTU/137225

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Nabumetone
 #2 Aspirin

2. Dose, frequency, & route used
 Plavix
 Coomadin

3. Therapy dates (if unknown, give duration)
 from/to (or best estimate)
 #1 _____
 #2 _____

4. Diagnosis for use (indication)

#1 CVT
 #2 CCA

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known)
 #1 _____
 #2 _____

7. Exp. date (if known)
 #1 _____
 #2 _____

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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6. model # FEB 08 2001

catalog # MEDWATCH CTU

serial #

lot#

other#

4. Operator of device
 health professional
 lay user/patient
 other:

5. Expiration date

7. If implanted, give date

8. If explanted, give date

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Initial reporter

1. Name, address & phone #

Dept Pharmacy
 Road

2. Health professional? Pharmacist

3. Occupation

4. Also reported to
 manufacturer
 user facility
 distributor

Individual Safety Report



3663835-9-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires 12/31/06
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **1373709**

A. Patient information

1. Patient identifier: [redacted] 2. Age at time of event: * 84 Years
or Date of birth: [redacted] 3. Sex: female male 4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death disability
 life-threatening congenital anomaly
 hospitalization - initial or prolonged required intervention to prevent permanent impairment/damage
 other

3. Date of event: 01/17/2001 4. Date of this report: 02/09/2001

5. Describe event or problem:
 Patient is a 84 year old male recently admitted by cardiology for cath but was discharged to be followed medically. Patient was discharged home on clopidrogel and aspirin. On 1/17/01 the patient presents to ER with mid epigastric pain and having had three bouts of bloody diarrhea. His HCT was 26.6 and HGB was 9.1. Patient was given 2 units of PRBCs. EGD did not reveal active bleed, however duodenal ulcer was detected.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (Product Name) (Label Strength) (Mfr/Labeler)
 #1 PLAVIX / 75MG / [redacted]
 #2 ASPIRIN 325MG EC / 325MG

2. Dose/frequency/Route used
 #1 75MG / QD / Oral
 #2 325MG / QD / Oral

3. Therapy dates (if known) (From To (or best estimate))
 #1 10/01/2000 - 01/17/2001
 #2 10/01/2000 - 01/17/2001

4. Diagnosis for use (separate indications with dates)
 #1 MI
 #2 MI

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known) 7. Exp. date (if known)
 #1 #2
 #1 #2

9. NDC # (for product problems only)
 #1 #2

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name
 2. Type of device
 3. Manufacturer name & address
 4. Operator of device:
 health professional
 lay user/patient
 other

5. Expiration date
 6. model # FEB 12 2001
 catalog # MEDWATCH CTU
 serial #
 lot #
 other #

7. If implanted, give date
 8. If explanted, give date

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on [redacted]

10. Concomitant medical products and therapy dates (exclude treatment of event):
DSS
 FEB 13 2001

E. Reporter (see confidentiality section on back)

1. Name: [redacted] phone #: [redacted]
 ZABLOCKI VA MEDICAL CENTER 5000 W NATIONAL AVE
 MILWAUKEE WISCONSIN
 United States JOHNSON, CHARLES M MILWAUKEE, VA, GOV

2. Health professional? yes no 3. Occupation: Pharmacist 4. Also reported to:
 manufacturer
 user/facility
 health care

5. If you do not want your identity disclosed to the manufacturer place an "X" in this box.



Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787
 or FAX to: 1-800-FDA-0178

Individual Safety Report



3665456-0-00-01

VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/00
See OMB statement on reverse

FDA Use Only

Triage unit
sequence #

137576

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

CDER

A. Patient information			
1. Patient identifier 7/00 case# 13 In confidence	2. Age at time of event: 80 Years or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 126 lbs or kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mm/dd/yyyy)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other: _____			
3. Date of event 07/21/2000 (mm/dd/yyyy)		4. Date of this report 02/12/2001 (mm/dd/yyyy)	
5. Describe event or problem			
81 yo was admitted to the medical floor for observation for presumed GI bleed with dropping Hct and Sob. Patient was receiving celccoxib 200mg aspirin 81mg, percodan q4h prn. Pt received 2 units of RPBC. Celecoxib and asa discontinued			
6. Relevant tests/laboratory data, including dates			
Hct23%			
<p>RECEIVED</p> <p>FEB 14 2001</p> <p>MEDWATCH CTU</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)			
1. Name (Product Name) (Labeled Strength) (Mfr/Labeier)			
#1	celecoxib / 200mg		
#2	asa / 81 mg		
2. Dose/Frequency/Route used		3. Therapy dates (if unknown, give duration)	
#1	200mg /qd /Oral	#1	From - To (or best estimate)
#2	81mg /qd /Oral	#2	-
4. Diagnosis for use (separate indications with commas)		5. Event abated after use stopped or dose reduced	
#1 Mediatinal Ca, mets to lung		#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
8. Event reappeared after reintroduction			
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply			
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply			
9. NDC # (for product problems only)			
-			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

D. Suspect medical device	
1. Brand name	
2. Type of device	
3. Manufacturer name & address	
DSS	
4. Operator of device	
<input type="checkbox"/> health professional	
<input type="checkbox"/> lay user/patient	
<input type="checkbox"/> other: _____	
5. Expiration date (mm/dd/yyyy)	
model # FEB 15 2001	
6. catalog #	
7. If implanted, give date (mm/dd/yyyy)	
serial #	
8. If explanted, give date (mm/dd/yyyy)	
lot #	
other #	
9. Device available for evaluation? (Do not send device to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mm/dd/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)			
1. Name		phone #	
VAMC		50 Irving Street N.W.	
Washington		District of Columbia 20420	
United States		Terrill.Washington@Med.VA.Gov	
2. Health professional?		3. Occupation	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		Pharmacist	
4. Also reported to			
<input type="checkbox"/> manufacturer			
<input type="checkbox"/> user facility			
<input type="checkbox"/> distributor			
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>			



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

FAX to:
1-800-FDA-0178

FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 137576



...VOLUNTARY reporting
th professionals of adverse
ts and product problems

Form Approved: OMB No. 0910-0291 Expires 12/31
See OMB statement on rev.

FDA Use Only
Triage unit
sequence # 137673

Page 001 of 001

A. Patient information

1. Patient identifier [redacted] In confidence	2. Age at time of event: <u>69</u> or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	---	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mo/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other _____

3. Date of event (mo/day/yr) 11-11-04

4. Date of this report (mo/day/yr)

5. Describe event or problem

1. GI BLEED

2. ORTHOSTATIC HYPOTENSION

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc)

CTU/137673

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1	<u>ASPIRIN</u>	#1	<u>8-17-04</u>
#2	<u>TICARZOSIN</u>	#2	<u>3-99</u>
2. Dose, frequency & route used		4. Diagnosis for use (indication)	
#1	<u>325mg QD</u>	#1	<u>CAD</u>
#2	<u>10mg QHS</u>	#2	
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
9. NDC # (for product problems only)		8. Event abated after use stopped or dose reduced	
		#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply	
		#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> does not apply	
10. Concomitant medical products and therapy dates (exclude treatment of event)			
<u>AMITRIPTYLINE</u>			

D. Suspect medical device

1. Brand name		4. Operator of device	
		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
2. Type of device		5. Expiration date (mo/day/yr)	
		<u>FEB 15 2001</u>	
3. Manufacturer name & address		7. If implanted, give date (mo/day/yr)	
RECEIVED <u>FEB 15 2001</u> MEDWATCH CTU		8. If explanted, give date (mo/day/yr)	
6. model #		9. Device available for evaluation? (Do not send to FDA)	
catalog #		<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on _____ (mo/day/yr)	
serial #		10. Concomitant medical products and therapy dates (exclude treatment of event)	
lot #			
other #			

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			
<u>OVERTON BROOKS VA MEDICAL CENTER</u> <u>510 EAST STONER AVENUE</u> <u>SHREVEPORT, LOUISIANA 71101-4295</u> <u>(318)-424-6001</u>			
2. Health professional?		3. Occupation	4. Also reported to
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<u>APL</u>	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			

FDA Mail to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178



VOLUNTARY reporting
health professionals of adverse
events and product problems

Form Approved: DMB No. 0610-0291 Expires: 1/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 138054

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ___ of ___

A. Patient information

1. Patient Identifier [Redacted]	2. Age at time of event: 74 or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 0 lbs or _____ kgs
-------------------------------------	---	---	---------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: not frequently reported

3. Date of event: 11/19/00 (mo/day/yr)

4. Date of this report: 2/16/01 (mo/day/yr)

5. Describe event or problem

The patient presented to the Emergency Room with a one week history of increasing fatigue and weakness. He reported having black, tarry stools for two days. He was admitted to the Medical ICU. An EGD was done which showed a bleeding ulcer. He was started on cimetidien 300 mg IV every 12 hours and lansoprazole 30 mg orally twice a day. He experienced one episode of hematemesis and maroon colored stools while in the ICU. He received several units of packed red blood cells and his hematocrit and hemoglobin stabilized. He was transferred to an internal medicine floor on 11/21/00 and continued to improve. He was discharged on 11/23/00 with cimetidine 400 mg, orally, twice a day and told to avoid all NSAIDs.

6. Relevant tests/laboratory data, including dates

	11/19	11/23
hemoglobin	4.3	9.3
hematocrit	14%	28%

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

The patient has a history of NSAIDs-induced GI bleed in 1996. He also has a history of oseoarthritis and chronic back pain.

CTV138054

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 50852-9787

or FAX TO:
1-800-FDA-0178

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 ibuprofen

#2 aspirin

2. Dose, frequency & route used

#1 unknown

#2 4 tablets a day

3. Therapy dates (if unknown, give duration) from to (or best estimate)

#1 unknown

#2 2 to 3 weeks

4. Diagnosis for use (indication)

#1 osteoarthritis and chronic back pain

#2 same

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1

#2

7. Exp. date (if known)

#1

#2

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

gabapentin, quinine, baclofen, trazodone, hydrocodone, and acetaminophen

D. Suspect medical device

1. Brand Name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional
 lay user/patient
 other

5. Expiration date (mo/day/yr)

6. model #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

Pharmacy and Therapeutics Subcommittee c/o Pharmacy Dept
[Redacted] Clinics
[Redacted] Drive
[Redacted]

2. Health professional
 yes no

3. Occupation
pharmacist

4. Also reported to

manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

Individual Safety Report



3668765-4-00-01

ATORY SAFETY
r use by user-facilities,
rs and manufacturers for
DATORY reporting

Approved by FDA on 09/27/01

Mfr report #
001-0981-M0100956

US/Div report #

FDA Use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information

1. Patient identifier	2. Age at time of event: 67 Y Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 185 lbs or [redacted] kgs
-----------------------	--	---	--

In confidence

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mo/day/yr) 10 / /00	4. Date of this report (mo/day/yr) 02/14/01
--	--

5. Describe event or problem

This consumer reports that her 67 year old husband, who takes a daily uncoated Aspirin, started Lipitor (atorvastatin) 80 mg daily for high cholesterol 4 to 5 years ago. In Oct00, he developed tiredness and painful ribs. He went for an unknown blood test in Oct00 and the result showed that he had lost a large amount of blood. He was admitted to the hospital and given 3 pints of blood. An endoscopy was performed and a small spot was found in the stomach that was not bleeding but they concluded that the bleeding could have occurred there. A colonoscopy was also performed and no other possible bleeding sites was found. He was started on Prevacid and the uncoated aspirin was stopped and he was switched to a daily enteric coated aspirin due to events. The physician suspects that the uncoated aspirin could have caused the possible bleeding in his stomach. As of 07Feb01, he has had no recurrence of any gastrointestinal bleeding problems.

6. Relevant tests/laboratory data, including dates

Oct00 - Unknown blood test result showed that he had lost a large amount of blood, endoscopy was performed and a small spot was found in the stomach, colonoscopy was also performed and no other possible bleeding sites were found.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

- HEART ATTACK (PAST): IN THE 1980'S
- clogged arteries(present)
- femoral artery replaced (past)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 ATORVASTATIN (ATORVASTATIN)

#2 UNCOATED ASPIRIN

2. Dose, frequency & route used	3. Therapy dates (if known, give duration) from to (or best estimates)
#1 80 mg (DAILY), Per oral	#1 unknown - ongoing
#2 UNKNOWN, Per oral	#2 unknown - ongoing

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 HIGH CHOLESTEROL	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> do n't apply Unk
#2 UNKNOWN	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> do n't apply

6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2

8. Event reappeared after reintroduction

#1 yes no do n't apply
Unk

#2 yes no do n't apply

9. NDC # - for product problems only (if known)

10. Concomitant medical products and therapy dates (exclude treatment of event)

1) (WARFARIN SODIUM)	UNKNOWN - ongoing
2) (ISOSORBIDE DINITRATE)	UNKNOWN - ongoing
3) (PENTOXIFYLLINE)	UNKNOWN - ongoing
4) (LANSOPRAZOLE)	UNKNOWN - ongoing

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42ND STREET NEW YORK NY 10017 USA (Initial Unit)	(212) 573-3129
3. Report source (check all that apply)	
<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other: _____	

4. Date received by manufacturer (mo/day/yr) 02/07/01	5. (A)NDA # 20-702
	IND # _____
	PLA # _____

6. If IND, protocol #	pre-1938 <input type="checkbox"/> yes
	OTC product <input type="checkbox"/> yes

7. Type of report (check all that apply)

5-day 15-day

10-day periodic

Initial follow-up # _____

8. Adverse event term(s)

1) EXCESSIVE BLEEDING

2) STOMACH ULCER

3) PAINFUL RIBS

4) TIREDNESS

9. Mfr. report number

001-0981-M0100956

E. Initial reporter

1. Name, address & phone #

[redacted]

USA

Phone # [redacted]

2. Health professional? <input type="checkbox"/> yes <input checked="" type="checkbox"/> no	3. Occupation	4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unl
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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report



3668765-4-00-02

Continuation Sheet for FDA-3500A Form

Page 2 of 2

Mfr. report # : 001-0981-M0100956

Date of this report : 02/14/01

C10. Concomitant medical products

Seq No. : 1
Concomitant Medical Product : (WARFARIN SODIUM)
Dose, frequency & route used : 1) Per oral

Seq No. : 2
Concomitant Medical Product : (ISOSORBIDE DINITRATE)
Dose, frequency & route used : 1) Per oral

Seq No. : 3
Concomitant Medical Product : (PENTOXIFYLLINE)
Dose, frequency & route used : 1) Per oral

Seq No. : 4
Concomitant Medical Product : (LANSOPRAZOLE)
Dose, frequency & route used : 1) Per oral *

FEB 21 2001

Individual Safety Report



3669314-7-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0918-0281 Expires: 12/31/00 See OMB statement on reuse

FDA Use Only (Internal)

Trace unit sequence # **138205**

Page **1** of **1**

A. Patient information

1. Patient identifier: **XX** in confidence
 2. Age at time of event: **75y**
 or Date of birth: _____
 3. Sex: female male
 4. Weight: _____ lbs or _____ kgs

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death (m/d/yy)
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other: _____

3. Date of event (m/d/yy): **10-31-00**
 4. Date of this report (m/d/yy): **2-23-01**

5. Describe event or problem

GASTROINTESTINAL BLEED: MELENA. Patient w/ H/O PUD taking lansoprazole, came to hospital c/o black stools & fatigue. She has been taking naproxen x years for hip pain. Recently she began taking 2 regular aspirin OD for headaches. C/O dizziness x 3 months; becoming progressively paler. In Emer Room: Hbg 5.6 transfused w/ 2 units PRBC. EGD showed 12-13mm deep central ulcer, clean based duodenal ulcer. Impression: H/O PUD + H. pylori w/ slow bleed x 3 months w/ recent increase likely to aspirin and chronic naproxen use. When discharged home H/H stable and asymptomatic.

*DISCHARGED 2 DAYS P
ADMISSION*

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
 #1 **NAPROXEN**
 #2 **ASPIRIN**

2. Dose, frequency & route used
 #1 _____
 #2 _____

3. Therapy dates (if unknown, give duration) (month for best estimate)
 #1 _____
 #2 _____

4. Diagnosis for use (indication)
 #1 _____
 #2 _____

5. Event abated after use stopped or dose reduced
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known)
 #1 _____
 #2 _____

7. Exp. date (if known)
 #1 _____
 #2 _____

8. Event reappeared after reintroduction
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only)
 #1 _____
 #2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other: _____

5. Expiration date (m/d/yy)

6. model # **MEDWATCH CTU**
 catalog # _____
 serial # _____
 lot # _____
 other # _____

7. If implanted, give date (m/d/yy)

8. If explanted, give date (m/d/yy)

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on _____ (m/d/yy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone # **DSS**
MED CTR
ST Rm **26 2001**

2. Health professional? yes no

3. Occupation **PHARMACIST**

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

FDA Mail to: MEDWATCH 5800 Fishers Land Rockville, MD 20852-9767 or FAX to: 1-800-FDA-0178



3674580-8-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved: OMB No. 0910-0291 Expires 12-31-00
See OMB statement on reverse

FDA Use Only

Triage unit sequence # **138 777**

A. Patient information

1. Patient identifier 1606 In confidence	2. Age at time of event: 77 Years or _____ Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	---	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) 01/29/2001

4. Date of this report (mm/dd/yyyy) 03/05/2001

5. Describe event or problem
Acute renal failure, gastrointestinal bleeding

6. Relevant tests/laboratory data, including dates
Creatinine clearance < 10 ml/min

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Ibuprofen / 200 mg / #2 BC Powder / 500 mg / -aspirin-	3. Therapy dates (if unknown, give duration) From To (or best estimate) #1 01/22/2001 - 01/29/2001 #2
2. Dose/Frequency/Route used #1 200 mg / q4-6 hours / Oral #2 unkno / / Oral	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1 Headache #2	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) #1 #2	7. Exp. date (if known) #1 #2
9. NDC # (for product problems only)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other:

5. Expiration date (mm/dd/yyyy)

6. model # **DSS**
catalog # **MAR 0 2001**
serial #
lot #

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name phone #

Pharm.D.
Ave.

United States

2. Health professional?
 yes no

3. Occupation
Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178

RECEIVED
MAR 06 2001
MEDWATCH CTU

MEDWATCH
MAR 06 2001
RECEIVED

CTU 138777

Individual Safety Report



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Form Approved by FDA 04/07/95

Mfr report #	SP-200001488
LF/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient ID	2. Age at time of event: or 89 YEARS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence			
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo day yr)	<input type="checkbox"/> life-threatening	<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other
3. Date of event (mo day yr)	4. Date of this report (mo day yr)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
# 3 ASPIRIN			
# 4			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/to (or best estimate))	
# 3		# 3 --/--/-- --/--/--	
# 4		# 4	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
# 3		# 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 4		# 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
# 3	# 3	# 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 4	# 4	# 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)			
# 3			
# 4			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office-name/address (& mailing site for devices)			2. Phone number
Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355-1307			(610) 889-4531
4. Date received by manufacturer (mo day yr)			3. Report source (check all that apply)
6. If IND, protocol #			<input type="checkbox"/> foreign
7. Type of report (check all that apply)			<input type="checkbox"/> study
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day			<input type="checkbox"/> literature
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic			<input type="checkbox"/> consumer
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up #			<input type="checkbox"/> health professional
9. Mfr. report number SP-200001488			<input type="checkbox"/> user facility
5. (A)NDA #			<input type="checkbox"/> company representative
IND #			<input type="checkbox"/> distributor
PLA #			<input type="checkbox"/> other
pre-1938 <input type="checkbox"/> yes			8. Adverse event term(s)
OTC product <input type="checkbox"/> yes			
E. Initial reporter			
1. Name, address & phone #			
2. Health professional?		3. Occupation	4. Initial reporter also sent report to FDA
<input type="checkbox"/> yes <input type="checkbox"/> no			<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> uni

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report



MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Page 1 of 2

Form Approved by FDA 04/07/95

Mfr report #	SP-200001488
UF/Dist report #	
FDA Use Only	

A. Patient information			
1. Patient ID	2. Age at time of event: or 89 YEARS Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo day yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input checked="" type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other			
3. Date of event 08/04/00 (mo day yr)	4. Date of this report 08/22/00 (mo day yr)		
5. Describe event or problem			
GI BLEEDING, DECREASED HEMATOCRIT: AN 89-YEAR-OLD FEMALE PATIENT UNDERWENT STENT PLACEMENT TO MID LAD AND RECEIVED REOPRO AND HEPARIN ON 04-AUG-00. DURING THE INFUSION, THE PATIENT DEVELOPED GI BLEEDING ASSOCIATED WITH GASTRIC EROSION. THE PATIENT'S HEMATOCRIT DROPPED FROM 30 TO 18. AT THE TIME OF THIS REPORT, THE BLEEDING HAD RESOLVED AND THE PATIENT IS RECOVERING, HOWEVER, SHE REMAINS IN INTENSIVE CARE. NO FURTHER INFORMATION WAS AVAILABLE.			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
# 1 REOPRO			
# 2 HEPARIN SODIUM			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration from/td (or best estimate)	
# 1 INTRAVENOUS IV		# 1 08/04/00 - - - / - / - -	
# 2		# 2 08/04/00 - - - / - / - -	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
# 1 STENT PLACEMENT TO MID LAD		# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 2 STENT PLACEMENT TO MID LAD		# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
# 1	# 1	# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 2	# 2	# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)			
# 1 0002-7140-01			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office-name/address (& mailing site (if devices)			2. Phone number
Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355-1307			(610) 889-4533
4. Date received by manufacturer (mo day yr)			3. Report source (check all that apply)
08/09/00			<input type="checkbox"/> foreign
6. If IND, protocol #			<input type="checkbox"/> study
7. Type of report (check all that apply)			<input type="checkbox"/> literature
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day			<input type="checkbox"/> consumer
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic			<input checked="" type="checkbox"/> health professional
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up #			<input type="checkbox"/> user facility
9. Mfr. report number			<input checked="" type="checkbox"/> company representative
SP-200001488			<input checked="" type="checkbox"/> distributor
5. (A)NDA #			<input type="checkbox"/> other
IND #			8. Adverse event term(s)
PLA # 93-1057			GI BLEEDING
pre-1938 <input type="checkbox"/> yes			DECREASED HEMATOCRIT
OTC product: <input type="checkbox"/> yes			
F. Initial reporter			
1. Name, address & phone #			
DR. [REDACTED] HOSPITAL [REDACTED] AVENUE [REDACTED] USA			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	CARDIOLOGIST	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> no	

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FDA Form 3500A(6/93)

3500A Facsimile

FEB 26 2001

370

Individual Safety Report



3678567-0-00-01

For use by user facilities, distributors and manufacturers for MANDATORY reporting

Form Approved by FDA 04/07/95

Mfr report #	SP-200001360
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 3

A. Patient information			
1. Patient ID	2. Age at time of event: 75 YEARS or _____ Date of birth: _____	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight _____ lbs or _____ kgs
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (mo day yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input checked="" type="checkbox"/> other MEDICALLY			
3. Date of event 07/26/00 (mo day yr)		4. Date of this report 08/08/00 (mo day yr)	
5. Describe event or problem			
GI BLEED: A 75-YEAR-OLD MALE RECEIVED REOPRO IN JUL-00 AND DEVELOPED A GI BLEED. APPROXIMATELY FOUR HOURS INTO THE INFUSION, THE BLEED WAS DETECTED. HIS HEMOGLOBIN DROPPED FROM 13 TO 10.6 AND THE "PATIENT'S PTT CHANGE WAS 66-150". HE WAS TREATED WITH A PLATELET TRANSFUSION. IT WAS REPORTED THAT THE PATIENT HAD UNDERGONE A COLON RESECTION TWO WEEKS PRIOR TO THE INFUSION. THE CALLER ALSO REPORTED THAT THE "PATIENT IS OK". NO FURTHER INFORMATION IS AVAILABLE. FOLLOW-UP INFORMATION WAS RECEIVED ON 27-JUL-00. REPORTEDLY, THE PATIENT RECEIVED REOPRO IN THE PAST AND EXPERIENCED A GI BLEED. IT WAS NOTED THAT THE SECOND GI BLEED WAS NOT AS SEVERE AS THE PREVIOUS BLEED. THE PHYSICIAN BELIEVES THAT THE PATIENT MAY HAVE AN UNDERLYING CONDITION WHICH PLACES THE PATIENT AT AN INCREASED RISK FOR BLEEDING WITH REOPRO. MEDICAL HISTORY AND DATES OF REOPRO ADMINISTRATION WERE PROVIDED. NO FURTHER INFORMATION			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) THE PATIENT IS APPROXIMATELY TWO WEEKS POST CORONARY INTERVENTION AND HAS HAD A PREVIOUS, RECENT COLON RESECTION.			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
# 1 REOPRO			
# 2 REOPRO			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
# 1 INTRAVENOUS		# 1 ---/--/-- ---/--/--	
# 2 Please see overflow page		# 2 07/26/00 - 07/26/00	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
# 1		# 1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
# 2 STENT OCCLUSION		# 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
# 1		# 1	
# 2		# 2	
9. NDC # - for product problems only (if known)			
# 1 0002-7140-01			
# 2 0002-7140-01			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office-name/address (& mfring site for devices)			2. Phone number
Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355-1307			(610) 889-4535
4. Date received by manufacturer (mo day yr)			5. (A)NDA #
C7/27/00			IND #
6. If IND, protocol #			PLA #
7. Type of report (check all that apply)			pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day			OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic			
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up #			
9. Mfr. report number			8. Adverse event term(s)
SP-200001360			GI BLEED
1. Name, address & phone #			2. Health professional?
DR. [REDACTED] MEDICAL COLLEGE OF [REDACTED] P.O. BOX [REDACTED] [REDACTED] USA			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no
3. Occupation			4. Initial reporter also sent report to FDA
CARDIOLOGIST			<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk

FDA

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FDA Form 3500A (6/93)

3500A Facsimile

FEB 25 2001

350

Individual Safety Report



3678567-0-00-02

For use by user facilities,
distributors and manufacturers for
MANDATORY reporting

Form Approved by FDA 04/07/95

Mfr report #	SP-200001360
UF/Dist report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information			
1. Patient ID	2. Age at time of event: or 75 YEARS Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
In confidence			
B. Adverse event or product problem			
1. <input type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death (no day yr)		<input type="checkbox"/> disability	
<input type="checkbox"/> life-threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization - initial or prolonged		<input type="checkbox"/> required intervention to prevent permanent impairment/damage	
<input type="checkbox"/> other			
3. Date of event (mo day yr)	4. Date of this report (mo day yr)		
5. Describe event or problem			
6. Relevant tests/laboratory data, including dates			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
# 3 HEPARIN SODIUM			
# 4 ASPIRIN			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
# 3 INTRAVENOUS 1		# 3 07/26/00 - 07/26/00	
# 4 ORAL		# 4 - / - / - - - - / - / - -	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
# 3 STENT OCCLUSION		# 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 4		# 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction	
# 3	# 3	# 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
# 4	# 4	# 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
G. All manufacturers			
1. Contact office-name/address (& mfrng site for devices)		2. Phone number (610) 889-4535	
Centocor, Inc. 200 Great Valley Parkway Malvern, Pennsylvania 19355-1307		3. Report source (check all that apply)	
		<input type="checkbox"/> foreign	
		<input type="checkbox"/> study	
		<input type="checkbox"/> literature	
		<input type="checkbox"/> consumer	
		<input type="checkbox"/> health professional	
		<input type="checkbox"/> user facility	
		<input type="checkbox"/> company representative	
		<input type="checkbox"/> distributor	
		<input type="checkbox"/> other	
4. Date received by manufacturer (mo day yr)	5. (A)NDA #		
	IND #		
	PLA #		
	pre-1938 <input type="checkbox"/> yes		
	OTC product <input type="checkbox"/> yes		
6. If IND, protocol #			
7. Type of report (check all that apply)			
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day			
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic			
<input type="checkbox"/> Initial <input type="checkbox"/> follow-up #			
8. Adverse event term(s)			
9. Mfr. report number SP-200001360			
E. Initial reporter			
1. Name, address & phone #			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no			
3. Occupation		4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unk	

FDA

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

FEB 26 2001

Individual Safety Report



3678567-0-00-03

D WATCH

(CONTINUED TEXT)

Page 3 of 3

A. Patient information

1. Patient ID:

G. All Manufacturers

1. Contact office-name/address

Centocor, Inc.

200 Great Valley Parkway

Malvern, Pennsylvania 19355-1307

Phone No. (610) 889-4535

9. Mfr. report number: SP-200001360

B. Adverse event or product problem - (continued from page 1)

2. Outcomes attributed to adverse event - other

SIGNIFICANT

5. Describe event or problem

IS AVAILABLE.

C. Suspect medications(s) - (continued from page 1)

1. Name / Dose Route Frequency

REOPRO

INTRAVENOUS BOLUS - INFUSION

FEB 26 2001
352

Individual Safety Report



3681920-2-00-01

Voluntary reporting with professionals of adverse events and product problems

Form Approved: OMB No. 0910-0201 Expires 12/31/01

FDA Use Only

Trials unit sequence # 139345

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient Identifier 939237 <small>(in confidence)</small>	2. Age at time of event: 72 Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	--	---	---

B. Adverse event or product problem

Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (m/d/yyyy) 1-25-01

4. Date of this report (m/d/yyyy) 3-15-01

5. Describe event or problem

pt. admitted EKG 2' weakness, fatigue, constipation, dcm(+), stools.

EKG = gastric ulcer

held coumadin discontinued verapamil + celebrex + ASA

6. Relevant tests/laboratory data, including dates

MEDWATCH

MAR 16 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

arthritis

cardiopathy by retrograde substrate therapy

pacemaker

at. fib, HTN, diabetes

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 <i>Coumadin 5mg ASA 81d</i>	#1 <i>daily</i>	#1 <i>?</i>
#2 <i>Celebrex 100mg</i>	#2 <i>daily</i>	#2 <i>?</i>
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced	
#1 <i>at. fib pacemaker</i>	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2 <i>arthritis</i>	#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
<i>30cc insulin</i>		
<i>lopressor</i>		
<i>regiment Verapamil</i>		

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device

health professional

lay user/patient

other:

5. Expiration date (m/d/yyyy)

6. If implanted, give date (m/d/yyyy)

7. If explanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on

10. Concomitant medical products and therapy dates (exclude treatment of event)

MAR 16 2001

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[Redacted]

[Redacted] center

[Redacted] rd

2. Health professional? yes no

3. Occupation *PHARMACIST*

4. Also reported to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mall to: MEDWATCH 5600 Fishers Lane Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

Individual Safety Report



3684162-X-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0201 Ex. Use: 12/21/99
See OMB statement at www.gsa.gov

FDA Use Only (Internal)

Trace unit
number: 139475

Page 1 of 1

A. Patient information

1. Patient identifier XX In confidence	2. Age at time of event: 69y or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
---	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (include year)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year): **11-27-00**

4. Date of this report (month/year): **3-19-01**

5. Describe event or problem

GASTROINTESTINAL BLEEDING. Patient w/ DM, HTN, CAD, & S/P PTCA taking Aspirin admitted to hospital for EGD for c/o dysphagia w/ GERD. Panendoscopy showed stomach: fundus, body subepitheal hemorrhage. DG: Subepitheal hemorrhage in body & fundus probably d/t aspirin. Treatment: Aspirin DC'd. To be FU in clinic.

6. Relevant tests/laboratory data, including dates

DSS

MAR 20 2001

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic or renal dysfunction, etc.)

MEDWATCH
MAR 19 2001

CTV139475

RECEIVED



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-0787
or FAX to:
1-800-FDA-0178

C. Suspect medication(s)

1. Name (give labeled strength & ml/labeler, if known)

#1 **ASPIRIN**

#2 _____

2. Dose, frequency & route used

#1 _____

#2 _____

3. Therapy dates (if unknown, give duration)
(month/year)

#1 _____

#2 _____

4. Diagnosis for use (Indication)

#1 _____

#2 _____

5. Event abated or use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6. Lot # (if known)

#1 _____

#2 _____

7. Exp. date (if known)

#1 _____

#2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9. NDC # (for product problems only)

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
MAR 20 2001

model # _____

catalog # **MEDWATCH CTU**

serial # _____

lot # _____

other # _____

4. Operator of device

health professional

lay user/patient

other: _____

5. Expiration date (month/year)

6. If implanted, give date (month/year)

7. If explanted, give date (month/year)

8. If explanted, give date (month/year)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

MED CTR
ST * Rm

2. Health professional? yes no

3. Occupation **PHARMACIST**

4. Also reports to

manufacturer

user facility

distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



For use by user-facilities, distributors and manufacturers for MANDATORY reporting

50317430

Mfr report # WAES 01021249
UF/Dist report #
FDA Use Only

A. Patient information

1. Patient identifier
2. Age at time of event: 75 years
3. Sex: Male
4. Weight: 173 pounds

B. Adverse event or product problem

1. Adverse event and/or Product problem
2. Outcomes attributed to adverse event: hospitalization-initial or prolonged
3. Date of event: 02/02/01
4. Date of this report: 03/13/01

5. Describe event or problem
This is in follow-up to report(s) previously submitted on 02/20/2001

Information has been received from medical records and a 75 year old white male physician with allergies to penicillin and morphine, is a non-smoker, non-drinker, has hypertension, wears bilateral hearing aids, has borderline diabetes mellitus, coronary artery disease and a history of three prior myocardial infarctions.

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates
Refer to Additional Page

DSS
MAR 19 2001



7. Other relevant history, including preexisting medical conditions
e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.

MEDICAL HISTORY: Barrett's esophagus; angioplasty; bilateral cataracts; coronary artery stent placement; endoscopy; discectomy; colonoscopy; atherectomy; gastrointestinal bleeding; ureterolithiasis; transurethral prostatectomy; myocardial infarction; knee prosthesis placement; hiatal hernia
CONCURRENT

(Continued on Additional Page)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 TAB VIOXX 25 mg
#2 aspirin 81 mg
2. Dose, frequency & route used
#1 Unk/Unk/PO
#2 Unk/Unk/Unk
3. Therapy dates (from/to) if unknown, give duration
#1 01/26/01 - 02/02/01
#2 Unk - Unk
4. Diagnosis for use (indication)
#1 pain
#2 Unknown
5. Event abated after use stopped or dose reduced
#1 yes
#2 no
6. Lot # (if known)
#1
#2
7. Exp date (if known)
#1
#2
8. Event reappeared after reintroduction
#1 yes
#2 no
9. NDC # - for product problems only (if known)
Unknown
10. Concomitant medical products and therapy dates (excluded treatment of event)
DIOVAN 7/7/01-Unk
IMDUR Unk -Unk

(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address
Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004
ATTN: Worldwide Product Safety
2. Phone Number
(610)397-2416
3. Report source (check all that apply)
health professional
4. Date received by manufacturer (mo/day/yr)
03/05/01
5. (A)INDA # 21042
IND #
PLA #
pre-1938
OTC product
9. Mfr report number
WAES 01021249

8. Adverse event term(s)
GASTROINTESTINAL BLEEDING; DUODENAL EROSION; HYPERKALEMIA; RENAL INSUFFICIENCY

E. Initial reporter

1. Name, address & phone #
Confidential Report
2. Health professional?
3. Occupation
M.D.
4. Initial reporter also sent report to FDA
yes

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MAR 6 2001



vitamin E, and isosorbide mononitrate. The patient reported that he had dinner on 01-FEB-2001 and felt well until he woke on 02-FEB-2001, at 3 a.m. with maroon bloody stools. The patient presented to the emergency room (ER) and was directly admitted. He felt slightly lightheaded when he stood up and had no associated symptoms. While in the ER, the patient had epigastric discomfort and vomited a large amount of dark red blood. On physical examination the patient was pleasant, alert and orientated; vital signs were stable; HEENT: revealed no pallor; icterus; or adenopathy; he had bruits radiating from an aortic ejection murmur into the right carotid; ABDOMEN: soft without masses; no distention or tenderness except in the subxyphoid location; no organomegaly; no abdominal scars; extremities showed no peripheral edema. Laboratory studies included: white count of 10.9; hemoglobin of 14.9; platelet count of 163,000; BUN of 59; creatinine of 1.6; calcium of 9.8; glucose of 211; sodium of 143; potassium of 6.5; chloride of 105; and CO2 of 29. An electrocardiogram (EKG) showed criteria of left ventricular hypertrophy (LVH) and large t-waves in leads V1 through V3. A chest x-ray revealed mild cardiomegaly; hiatal hernia; and linear scarring or atelectasis on the right side. An abdominal x-ray resulted in a nonspecific abdomen. The patient was diagnosed with an upper GI bleed probably on the basis of aspirin and rofecoxib induced either esophagitis or ulcer disease. The elevated potassium (6.5) that may be spurious or related to a combination of blood in his GI tract, rofecoxib, and renal insufficiency. The patient was treated with D5 half normal saline; hyperkalemia was treated with 10 units of insulin subcutaneous; and his medications were held pending an upper endoscopy. Therapy with rofecoxib was interrupted. The patient had an upper endoscopy which revealed gastrointestinal (GI) bleeding from the second portion of the duodenum with etiology of bleeding that was unable to be located; duodenal erosions in the second portion of the duodenum; atrophic gastritis (Incidental finding); a large hiatal hernia with multiple erosions and non bleeding in nature; and Barrett's esophagus extending to 25 cm. The patient remained stable during the procedure. Post endoscopy the plan of care was to observe the patient closely; continue IV fluids with insulin coverage; recheck his potassium and correct if necessary; hemoglobin and hematocrit every six hours; type and cross; physician to be notified of any active bleeding or hemoglobin less than ten; follow-up EKG; and CBC. Subsequently, the patient recovered and was discharged on 03-FEB-2001. On 05-FEB-2001, laboratory studies showed a BUN of 23; creatinine of 1.3; BUN/creatinine ratio of 18; and potassium of 4.7. The physician felt that the GI bleed was related to therapy with rofecoxib and aspirin induced either esophagitis or ulcer disease. The hyperkalemia which maybe spurious or may be related to a combination of blood in his GI tract, rofecoxib, and renal insufficiency.

Atrophic gastritis was found to be an Incidental finding. Aspirin and rofecoxib were considered secondary suspects. Additional information is not expected.

DSS

MAR 19 2001

6. Relevant tests/laboratory data, including dates

DIAGNOSTIC TEST

Tests	Date	Value	Unit	Normal Range
abdominal X-ray	02/02/01			
Comment:		showed nonspecific abdomen, degenerative changes seen in the spine		
chest X-ray	02/02/01			
Comment:		mild cardiomegaly; hiatal hernia; linear scarring or atelaectasis on the right		
electrocardiogram	02/02/01			
Comment:		showed criteria of LVH; lg. T waves in V1 to V3		
endoscopy	02/02/01			
Comment:		revealed GI bleed; duodenal erosions; atrophic gastritis; lg hiatal hernia; Barrett's esophagus		

LABORATORY RESULTS

Tests	Date	Value	Unit	Normal Range
WBC count	02/02/01	10.9		
hemoglobin	02/02/01	14.9		
platelet count	02/02/01	163,000		
serum blood urea nitrogen	02/02/01	59		
serum calcium	02/02/01	9.8		
serum chloride	02/02/01	105		
serum creatinine	02/02/01	1.6		
serum glucose	02/02/01	211		
serum potassium	02/02/01	6.5		
serum sodium	02/02/01	143		
total serum carbon dioxide	02/02/01	29		
WBC count	02/05/01	7.0		
hematocrit	02/05/01	34.1%		
hemoglobin	02/05/01	11.7	g/dL	
lymphocyte count	02/05/01	2.1		
mean corpuscular hemoglobin conc	02/05/01	34.3		
platelet count	02/05/01	205	K/ul	
serum BUN creatinine ratio	02/05/01	18	calc	6 - 25
serum blood urea nitrogen	02/05/01	23	mg/dL	7 - 30

MAR 16 2001



PT: [REDACTED]
DA: 02/02/2001
DO: 02/02/2001
DR: [REDACTED]

UNIT#: [REDACTED] RM#: [REDACTED]
ACCT#: [REDACTED]
DOB: 06/22/25

OPERATIVE REPORT
PAGE 1

FDA ATTACHMENT

PREOPERATIVE DIAGNOSIS:
1. GI BLEED.

POSTOPERATIVE DIAGNOSES:
1. GI BLEEDING FROM SECOND PORTION OF THE DUODENUM WITH ETIOLOGY OF BLEEDING UNABLE TO BE LOCATED.
2. DUODENAL EROSIONS IN THE SECOND PORTION OF THE DUODENUM.
3. ATROPHIC GASTRITIS.
4. LARGE HIATAL HERNIA WITH MULTIPLE EROSIONS, ~~NONBLEEDING IN~~ NATURE.
5. BARRETT'S ESOPHAGUS EXTENDING TO 25 CM.

PROCEDURE: UPPER ENDOSCOPY.

SURGEON: [REDACTED]

ANESTHESIA: DEMEROL 50 MG AND VERSED 3 MG. GLUCAGON 0.5 MG GIVEN TO TRY TO RELAX DESCENDING DUODENUM.

DESCRIPTION OF PROCEDURE:
PRIOR TO THE PROCEDURE, AN INFORMED CONSENT WAS OBTAINED. THE RISKS OF PERFORATION, BLEEDING, INFECTION AND SEDATION WERE REVIEWED.

WITH ANESTHETIC SPRAY AND THE PATIENT COMFORTABLE, AN UPPER ENDOSCOPY WAS ADVANCED THROUGH THE ESOPHAGUS WHERE A LARGE HIATAL HERNIA WAS EVIDENT. THERE EVIDENCE OF BARRETT'S EXTENDING TO 25 CM FROM THE INCISORS. THERE WAS NO BLEEDING SEEN IN THE ESOPHAGUS OR THE STOMACH. THE STOMACH WAS OBVIOUSLY ATROPHIC IN APPEARANCE. THIS EXTENDED THROUGHOUT THE ENTIRE STOMACH. THE DUODENUM WAS ENTERED AND THE DUODENAL BULB WAS NORMAL. FROM THE DESCENDING DUODENUM, THERE WERE EROSIONS SEEN.

ONCE I GOT BEYOND THE AREA WHERE BILE WAS MATERIALIZING FROM THE DUODENAL WALL. THERE WAS BLOOD WITH BLOOD CLOT. THIS AREA WAS WASHED AT LEAST FOR 15 TO 20 MINUTES CAREFULLY TRYING TO FIGURE OUT WHERE BLEEDING SOURCE WAS COMING FROM. I COULD NOT DEFINE ANY SPECIFIC FINDINGS. THERE WERE EROSIONS MANIFESTED AS SLIT LIKE EROSIONS WITHIN THE AREAS OF THE DUODENAL WALL. I WENT BEYOND THIS AREA WHERE THE AREA APPEARED MORE CLEAR AND NO SIGNS OF BLEEDING.

ON WITHDRAWING INTO THE AREA JUST BEYOND THE AMFULLA, THERE WAS AREAS OF OLD BLOOD SEEN. THIS AREA WAS WASHED CLEAR TRYING TO

DSS

MAR 19 2001

MAR 16 2001



3684195-3-00-05

INFORMATION MANAGEMENT REPORT

PT: [REDACTED] UNIT#: [REDACTED] RM#: [REDACTED]
 DA: 02/02/2001 ACCT#: [REDACTED]
 DR: [REDACTED] DOB: [REDACTED]

HISTORY & PHYSICAL
 PAGE 1

FDA ATTACHMENT

CHIEF COMPLAINT: GI BLEED.

HISTORY OF PRESENT ILLNESS: THIS IS A 75 YEAR OLD SEMI-RETIRED INTERNIST WHO LIVES IN [REDACTED] AND [REDACTED] HE PRESENTS TODAY HAVING WOKEN UP EARLY THIS MORNING WITH MAROON BLOODY STOOLS. EPIGASTRIC DISCOMFORT AND SUBSEQUENTLY HAD BLOODY EMESIS. HE PRESENTED TO THE EMERGENCY ROOM WHERE HE WAS DIRECTLY ADMITTED BY [REDACTED] AFTER VITAL SIGNS WERE OBTAINED. THE PATIENT REPORTS THAT HE WAS FEELING WELL AND ATE DINNER LAST NIGHT WHICH HE REPORTS WAS NOT A VERY GOOD DINNER. BUT FELT OTHERWISE FINE UNTIL THIS PRESENTATION. HE DID FEEL SLIGHTLY LIGHTEADED WHEN HE WOULD STAND UP. HE HAS NOT BEEN HAVING ASSOCIATED SYMPTOMS. HE DOES HAVE A PAST MEDICAL HISTORY OF GI BLEED. BARRETT'S ESOPHAGUS. HIATAL HERNIA. HE HAS HAD PRIOR COLONOSCOPIES. THE EXACT CAUSE OF HIS GI BLEED THREE YEARS AGO WAS NOT DELINEATED. LAST ENDOSCOPY WAS ABOUT A YEAR AGO FOR BARRETT'S SURVEILLANCE AND THIS WAS DONE IN [REDACTED] HE REPORTS THAT DR. [REDACTED] AT ONE POINT QUESTIONS WHETHER HE HAD CROHN'S DISEASE. HE DOES TAKE VIOXX AND ASPIRIN IN COMBINATION WITH HIS OTHER MEDICATIONS.

DSS

MAR 19 2001

PAST MEDICAL HISTORY: HE HAS A HISTORY OF BILATERAL HEARING AIDS. BILATERAL CATARACTS. BORDERLINE DIABETES. HYPERTENSION. THREE MYOCARDIAL INFARCTIONS. STATUS POST ANGIOPLASTY AND ATHERECTOMY AND SUBSEQUENT LADD STENT. HE HAS ALSO HAD A LEFT TOTAL KNEE REPLACEMENT. L4-L5 DISCECTOMIES. HE HAS HAD A TUP WITH REMOVAL OF URETERAL STONES AND BARRETT'S ESOPHAGUS AND HIATAL HERNIA.

MEDICATIONS: VIOXX 25 MG.. BABY ASPIRIN 81 MG.. DIOVAN 160 MG.. ATENOLOL 50 MG.. MAXZIDE 37.5/25. VITAMIN E 400 IU. IMOUR 80 MG. PER DAY.

ALLERGIES: PENICILLIN AND MORPHINE.

FAMILY HISTORY: NO REPRESENTATIVE ABNORMALITIES RELATED TO THIS ADMISSION.

SOCIAL HISTORY: AS NOTED ABOVE. SEMI-RETIRED. HE IS A NON-SMOKER AND NON-DRINKER.

PHYSICAL EXAMINATION: HE IS A PLEASANT, ALERT AND ORIENTED GENTLEMAN. VITAL SIGNS CHARTED IN THE EMERGENCY ROOM AND APPEAR TO BE PRESENTLY STABLE. THE PATIENT FELT SLIGHTLY ORTHOSTATIC HIMSELF.

MAR 16 2001



3684195-3-00-06

FDA ATTACHMENT

HEALTH INFORMATION MANAGEMENT REPORT

PT: [REDACTED] UNIT#: [REDACTED] RM#: [REDACTED]
 DA: 02/02/2001 ACCT#: [REDACTED]
 DO: 02/02/2001 DOB: [REDACTED]
 DR: [REDACTED]

PAGE 2

SEE IF MORE BLOOD WOULD MATERIALIZE. NO OTHER BLOOD MATERIALIZED. I STILL COULD NOT LOCATE A DISCRETE BLEEDING SOURCE. THE STOMACH WAS ONCE AGAIN INSPECTED AND THEN THE SCOPE WAS WITHDRAWN. THE PATIENT WAS VERY STABLE THROUGH THE PROCEDURE. I AM IN THE PROCESS OF CORRECTING HYPERKALEMIA WITH INSULIN AND GLUCOSE.

RECOMMENDATIONS/PLANS:

1. OBSERVE THE PATIENT CLOSELY.
2. CONTINUE THE PATIENT ON IV FLUIDS WITH INSULIN COVERAGE.
3. RECHECK HIS BMP TO SEE THAT HIS POTASSIUM IS CORRECTED WITHIN THE NEXT FEW HOURS. IF NECESSARY, GIVE FURTHER POTASSIUM CORRECTION.
4. HE IS TO BE TYPED AND CROSSED AND GET H&H Q.6H.
5. I AM TO BE NOTIFIED IF HE HAS SIGNS OF ACTIVE BLEEDING OR HIS HEMOGLOBIN OF LESS THAN 10.
6. WILL FOLLOW-UP ON HIS EKG, BMP AND CBC IN THE A.M.

D: 02/02/2001 [REDACTED] T: 02/02/2001
 [REDACTED]

DSS

MAR 19 2001



3684195-3-00-07

INFORMATION MANAGEMENT REPORT

FDA ATTACHMENT

PT: [REDACTED]
DA: 02/02/2001
DR: [REDACTED]

UNIT#: [REDACTED] RM#: [REDACTED]
ACCT#: [REDACTED]
DOE: [REDACTED]
PAGE 2

HEENT REVEALS NO PALLOR, ICTERUS, OR ADENOPATHY. HE HAS BRUITS RADIATING FROM AN AORTIC EJECTION MURMUR INTO THE RIGHT CAROTID. HIS ABDOMEN IS SOFT WITHOUT MASSES, DISTENTION, OR TENDERNESS, EXCEPT IN THE SUBXIPHOID LOCATION. THERE IS NO ORGANOMEGALY AND NO ABDOMINAL SCARS. EXTREMITIES SHOW NO PERIPHERAL EDEMA.

LABORATORY STUDIES: WHITE COUNT 10.9. HEMOGLOBIN 14.9. PLATELET COUNT 163,000. BUN 59. CREATININE 1.6. CALCIUM 9.8. GLUCOSE 211. SODIUM 143. POTASSIUM 6.5. CHLORIDE 105. CO2 29.

CHEST AND ABDOMINAL X-RAYS ARE PENDING.

ECG SHOWS CRITERIA OF LVH. HE HAS LARGE T-WAVES IN THE V1 THROUGH V3 LEADS.

IMPRESSION:

1. UPPER GI BLEED PROBABLY ON THE BASIS OF ASPIRIN AND VIOXX INDUCED EITHER ESOPHAGITIS OR ULCER DISEASE.
2. ELEVATED POTASSIUM WHICH MAY BE SPURIOUS OR MAY BE RELATED TO A COMBINATION OF BLOOD IN HIS GI TRACT, VIOXX AND RENAL INSUFFICIENCY.
3. HISTORY OF BORDERLINE DIABETES.
4. HYPERTENSION.
5. CORONARY ARTERY DISEASE.

DSS

MAR 19 2001

PLAN:

1. CHANGE HIS IV FLUIDS TO A DS HALF NORMAL.
2. GIVE 10 UNITS OF INSULIN SUBCUTANEOUS NOW FOR HYPERKALEMIA AND FOR BLOOD SUGAR COVERAGE IN CONJUNCTION WITH THE CHANGE IN HIS IV FLUIDS AND RECHECK OF HIS POTASSIUM.
3. WE WILL HOLD HIS MEDICATIONS PENDING AN UPPER ENDOSCOPY AND PROCEED WITH URGENT UPPER ENDOSCOPY BASED UPON HIS PRESENTATION. HIS IS TYPED AND SCREENED AND, THEREFORE, WE WILL HAVE BLOOD AVAILABLE IF THE ENDOSCOPY DETERMINES THE NEED FOR THIS.
4. WE WILL GET ADDITIONAL CONSULTATIONS IF NEEDED.

D: 02/02/2001 [REDACTED] T: 02/02/2001

MAR 16 2001



3684195-3-00-08

~~patient~~ patient

~~_____~~
~~_____~~
~~_____~~

LABORATORY

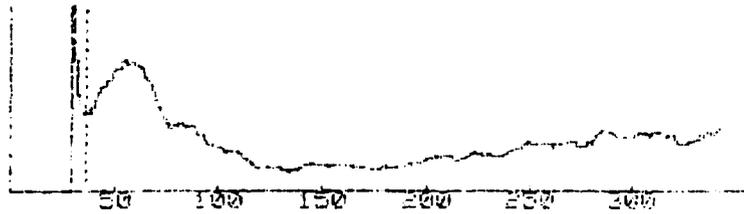
HP

CELL-DYN 1400 SPECIMEN DATA REPORT

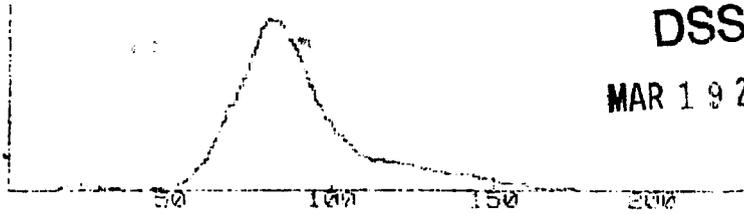
Specimen ID: 10001
Patient: ~~_____~~

Feb 05 2001 11
Operator: ~~_____~~
Sequence #: ~~_____~~

WBC: 7.0 K/UL
LYM: 5.1 29.5 XL WBC
GRAN: 4.9 70.5 XC



RBC: 4.11 M/UL
HGB: 11.7 g/dL
HCT: 34.1 %
MCV: 83. FL
MCH: 28.5 PG
MCHC: 34.3 g/dL



DSS

MAR 19 2001

PLT: 200. K/UL



[Handwritten signature]
wife interested

MAR 16 2001



Clinical Laboratory Report

FDA ATTACHMENT

Complete Report

02/05/2001	09:40am	02/05/2001	02/06/2001
DATE Drawn	TIME Drawn	DATE Received	DATE of Report
M	75		
SEX	AGE	HEIGHT/ID #	ACCOUNT NUMBER
		SS #	STATEMENT NUMBER
COMMAND			

Test Name	Results	Units	Reference Range	S
10165 BASIC METABOLIC PANEL				
UREA NITROGEN (BUN)	23	MG/LL	7- 30	
CREATININE	1.3	MG/DL	0.5- 1.4	
BUN/CREATININE RATIO	18	(CALC)	6- 25	
SODIUM	146	MEQ/L	135- 148	
POTASSIUM	4.7	MEQ/L	3.5- 5.3	
CHLORIDE	106	MEQ/L	95- 108	
CARBON DIOXIDE	28	MEQ/L	20- 32	
CALCIUM	8.8	MG/DL	8.5- 10.3	

COMMENTS:

Performing Laboratory Site Legend...

MI



DSS

MAR 19 2001

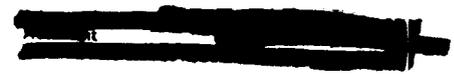
*** END OF REPORT ***

Impaired BUN ↓

(B)

[Signature]

Legend ↑ High ↓ Low ✖ Abnormal C Corrected I Incomplete P Preliminary





ORDER ENTRY TRANSCRIPTION RESULTS

PAGE 01

[REDACTED]

[REDACTED] N 2/02/2001 [REDACTED] TEA
[REDACTED] DSS [REDACTED]

GI BLEED
ABD FLAT UPRIGHT

ABDOMEN SERIES:
AIR IS SEEN IN NONDISTENDED LARGE AND SMALL BOWEL LOOPS. THERE IS NO
BOWEL DISTENTION OR PATHOLOGIC AIR/FLUID LEVEL. THERE IS NO SIGN OF
FREE INTRAPERITONEAL AIR. THE FSOAS MARGINS ARE SYMMETRIC.
DEGENERATIVE CHANGES ARE SEEN IN THE SPINE.

IMPRESSION:
NONSPECIFIC ABDOMEN.

[REDACTED]
THIS DOCUMENT IS ELECTRONICALLY SIGNED [REDACTED] 02/02/01
02/02/01 [REDACTED] [REDACTED] [REDACTED]

DSS

MAR 19 2001



3684195-3-00-11

FDA ATTACHMENT

ORDER ENTRY TRANSCRIPTION RESULTS

PAGE 01

[REDACTED]

[REDACTED] 2/02/2001 [REDACTED]

[REDACTED] DOB [REDACTED]

GI BLEED
CXR SINGLE VIEW
1381731700
SINGLE VIEW CHEST:
THERE IS LEFT VENTRICULAR PROMINENCE OF THE HEART. THERE IS A LARGE
HIATAL HERNIA. THERE IS SOME LINEAR SCARRING OR ATELECTASIS IN THE
RIGHT MID-LUNG ZONE. THERE IS NO INFILTRATE OR EDEMA.

IMPRESSION:
MILD CARDIOMEGALY.
HIATAL HERNIA.
LINEAR SCARRING OR ATELECTASIS ON THE RIGHT.

[REDACTED]
THIS DOCUMENT IS ELECTRONICALLY SIGNED [REDACTED] 02/02/01

02/02/01 [REDACTED] [REDACTED] [REDACTED] [REDACTED]

DSS

MAR 19 2001

MAR 16 2001



3685034-7-00-01

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/04 See OMB statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

FDA Use Only (MB)

Triage and sequence #

139597

A. Patient information

1. Patient identifier 1084 In confidence	2. Age at time of event: 73 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
--	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (m/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/day/yr) 9/29/00

4. Date of this report (m/day/yr) _____

5. Describe event or problem

4 day Hx of black, tarry stools
Dizziness on standing, weakness
Gnainc(+)
Piroxicam & ASA Dcd.
Put on Celebrex.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Mult. GI bleeds in past
RA x 3 years BPT1
CAD
HTN
anemia CT/139597

DSS
MAR 2 1 2001

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Piroxicam
#2 ASA

2. Dose, frequency & route used

#1 20mg qd
#2 100mg qd

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 8/28/00 -> 9/29/00
#2 -> 9/29/00

4. Diagnosis for use (indication)

#1 RA
#2

5. Event abated after use stopped or dose reduced

#1 yes no doesn't apply
#2 yes no doesn't apply

6. Lot # (if known) #1 _____ #2 _____

7. Exp. date (if known) #1 _____ #2 _____

8. Event reappeared after reintroduction

#1 yes no doesn't apply
#2 yes no doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment of event)

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other

5. Expiration date (m/day/yr)

6. model # MAR 2 1 2001
catalog # MEDWATCH CTU
serial #
lot #
other #

7. If implanted, give date (m/day/yr)

8. If explanted, give date (m/day/yr)

9. Device available for evaluation? (Do not send to FDA)
 yes no returned to manufacturer on _____ (m/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
VA HOSPITAL (119)
7400 MERTON MINTER BLVD.
SAN ANTONIO, TX 78284

2. Health professional? yes no

3. Occupation Pharm D

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to _____ in this box.



3685207-3-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/04 See OMB statement on reverse

FDA Use Only (AHFS)

Trace and sequence #

139509

Page ___ of ___

A. Patient information

1 Patient identifier 18430 In confidence	2 Age at time of event: or Date of birth: [redacted]	3 Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4 Weight 45 lbs or kgs
--	--	--	---------------------------------

B. Adverse event or product problem

1 Adverse event and/or Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply):

death disability congenital anomaly

life-threatening required intervention to prevent permanent impairment/damage

hospitalization - initial or prolonged other

3 Date of event: 7/26/00

4 Date of this report: 1/16/01

5 Describe event or problem

Presents abdominal pain. Felt fullness then sharp pain (10 out of 10). Stool was normal that day but had one bowl of dark coffee ground emesis at hospital. Gastric ulcer seen in stomach. Started on IV Pepoid & sent home on Prilosec upon discharge.

6 Relevant tests/laboratory data, including dates

DSS
MAR 21 2001

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepato-renal dysfunction, etc.)

HTN
CHF
hypercholesterolemia
atherosclerosis
COPD
DJD

gout
cataract
detached retina
diverticulitis
cerebrovascular disease
breast cancer
renal insufficiency

hysterectomy
hypothyroidism
depression

C. Suspect medication(s)

1 Name (give labeled strength & mfr label, if known)

#1 Ecotrin 100 mg qd

#2

2 Dose, frequency & route used

#1 100 mg po qd

#2

3 Therapy dates (if unknown give duration)

#1 ?

#2

4 Diagnosis (for use indications)

#1 ?

#2

5 Event abated after use stopped or dose reduced

#1 yes no doesn't apply

#2 yes no doesn't apply

6 Lot # (if known)

#1

#2

7 Exp. date (if known)

#1

#2

8 Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

9 NDC # (for product problems only)

10 Concomitant medical products and therapy dates (exclude treatment of event)

Lasix 80mg bid
Vasotec 10mg qd
Cardene 120mg qd
Lorazepam 2mg qd

Amoxicillin 600mg qd
Allopurinol 100mg bid
Valium 10mg qd
Skelaxin 400mg qd

Bethanechol 16mg tid
Docusate 50mg bid
Metformin

D. Suspect medical device

1 Brand name

2 Type of device

3 Manufacturer name & address

4 Operator of device

health professional
 lay user/patient
 other

5 Expiration date

6 model # MEDWATCH CTU

7 If implanted, give date

8 If explanted, give date

9 Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on

10 Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone

[redacted]

2 Health professional? yes no

3 Occupation
Pharmacy Intern

4 Also reported to

manufacturer
 user/facility
 distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.

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Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

OR FAX to:
1-800-FDA-0178

FOA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTV 139509



3685330-3-00-01

VOLUNTARY reporting by health professionals of adverse events and product problems

Form Approved: OMB No. 0910-0201 Expires: 12/31/94 See OMB Statement on reverse

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FDA Use Only (MB)

Triage unit sequence # **139575**

MAOPC Page ___ of ___

A. Patient information

1. Patient Identifier 1080 In confidence	2. Age at time of event: 61 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ___ lbs or ___ kgs
---	---	---	---------------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (m/day/yr)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/day/yr) **9/7/00**

4. Date of this report (m/day/yr) **12/15/00**

5. Describe event or problem

**GI Bleed, Anemia
MEG pain x 1 month PTA
hematemesis, fatigue
DOE. Given 4u PRBC**

**EGD revealed ulcerations
in pylorus, duodenum,
antrum.**

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

DSS
MAR 2 1 2001

C. Suspect medication(s)

1. Name (give labeled strength & mlr/labeler, if known)		3. Therapy dates (if unknown, give duration from/to or best estimate)	
#1	Aspirin	#1	8/7/00 - 9/7/00
#2		#2	
2. Dose, frequency & route used		4. Diagnosis for use (indication)	
#1	4-9 4-6h	#1	abdom. pain
#2		#2	
5. Event abated after us- stopped or dose reduced		8. Event reappeared after reintroduction	
#1	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#1	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)		7. Exp. date (if known)	
#1		#1	
#2		#2	
9. NDC # (for product problems only)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

D. Suspect medical device

1. Brand name		4. Operator of device	
2. Type of device		<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other	
3. Manufacturer name & address		5. Expiration date (m/day/yr)	
RECEIVED MAR 20 2001			
6. model # MEDWATCH CTU		7. If implanted, give date (m/day/yr)	
catalog #		8. If explanted, give date (m/day/yr)	
serial #			
lot #			
other #			
9. Device available for evaluation? (Do not send to FDA)			
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (m/day/yr)			
10. Concomitant medical products and therapy dates (exclude treatment of event)			

E. Reporter (see confidentiality section on back)

1. Name, address & phone #			4. Also reported to:
VA HOSPITAL (119) 7400 MERTON MINTER BLVD. SAN ANTONIO, TX 78284			
2. Health professional?	3. Occupation		
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Pharm D	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>			

CTV139575

FDA Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178



3685477-1-00-01

CDER

MEDWATCH

THE FDA MEDICAL PRODUCTS ADVERSE EVENT PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

FD-302 (Rev. 12-17-99)

Case # **139643**

Page 1 of 1

A. Patient information

1. Patient identifier: 17440	2. Age at time of event: 68	3. Sex: <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight: ____ lbs or ____ kg
5. Date of event: 10-27-00	6. Date of birth: _____		

B. Adverse event or product problem

Adverse event and/or Product problem (e.g., defect/malfunction)

1. Outcomes attributed to adverse event (check all that apply):

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other _____

3. Date of event: **10-27-00** 4. Date of this report: **11-27-00**

5. Describe event or problem

Pt. presents to ER w/ vomiting past 2 days, unable to keep food down x 3 days. Reports feeling out of it and occasional LLB pain. ⊕ Blood in stool per patient. No chronic renal failure (no HD), now presenting w/ acute on chronic renal failure and UGIB x 4GIB.

Fluids (1.5L) given, 2 units PRBCs, sent to med.

Renal, GI Follow-up.

* Baseline Cr = 3.6
Admission Cr = 3.5

* Admission Hgb = 6.8 g/dL

* Admission K⁺ = 6.1
Baseline K⁺ = 3.5

* Endoscopy - 2 on ulcer in antrum of stomach, multiple ulcers in several portions of duodenum.

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known):

#1 **FOSINOPRIL**

#2 **ASPIRIN / ANACIN**

2. Dose, frequency & route used:

#1 **20mg PO Daily**

#2 **UNKNOWN DOSES (26-8 TABS PER HD NOTE PER DAY)**

3. Therapy dates (start/stop/reluctant, if known):

#1 _____

#2 _____

4. Diagnosis for use (indication):

#1 _____

#2 _____

5. Event tabulated after use stopped or dose reduced:

#1 Yes No

#2 Yes No

6. Event reappeared after reintroduction:

#1 Yes No

#2 Yes No

7. Lot # (if known):

#1 _____

#2 _____

8. Exp. date (if known):

#1 _____

#2 _____

9. NDC # (for product problems only):

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (start/stop/reluctant, if known):

Send to FDA

D. Suspect medical device

1. Brand name:

2. Type of device:

3. Manufacturer name & address:

(P+T: Review needed)

→ Send To Ms. Mosko, NP

→ She reviewed it further.

→ P+T: ADRx Severe

→ Send To FDA

4. Operator of device:

health professional

lay user/patient

other _____

5. Expiration date (if applicable):

6. Replacement date (if applicable):

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MAR 21 2001

MEDWATCH CTU

E. Reporter (see instructions on back)

1. Name (last, first, middle initial):

[Redacted] Pharm D

2. Title:

Michigan pharmacist

3. Institution:

Phil VA MC, Phil 19104

4. Address:

5. City/State/Zip:

6. Telephone:

7. Fax:

8. E-mail:

9. Signature:

[Redacted]

10. Date:



MedWatch
800-FDA-1088
FDA Website: www.fda.gov

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 139643
Entered in computer

DSS
Vol 55 Jan 1 1998 Am J Health-Syst Pharm 85
MAR 21 2001



3688075-9-00-01

Merck Human Health Division

For use by user-facilities, distributors and manufacturers for MANDATORY reporting

Merck Facsimile of FDA Form 3500A Approved by FDA (10/21/93)

Mfr report # WAES 01030805
UF/Dist report #
FDA Use Only

NO ATTACHMENT

50318335

A. Patient information

1. Patient identifier: [redacted]
2. Age at time of event: 71 years
3. Sex: [X] Male
4. Weight: Unk

B. Adverse event or product problem

1. [X] Adverse event and / or [] Product problem
2. Outcomes attributed to adverse event: [X] hospitalization-initial or prolonged
3. Date of event: 01/??/01
4. Date of this report: 03/20/01

This is in follow-up to report(s) previously submitted on 03/13/2001

Information has been received from a consumer concerning a 71 year old male patient with allergies to dust, cat, dog and grass and a significant history of peptic ulcer disease who was placed on therapy with montelukast sodium, tablet, 10 mg, daily, for the treatment of asthma for several months (duration not reported). Concomitant therapy included simvastatin (MSD), iron (unspecified), lisinopril (ZESTRIL), ibuprofen (Advil) and pantoprazole sodium (PROTONIX). In approximately January 2001, the patient fell and experienced a painful shoulder. The patient began to take "a lot of aspirin" (total daily dose, duration and indication not reported) while still on therapy with montelukast sodium. In January 2001 the patient's hemoglobin was 14.5. The patient was hospitalized from 07-FEB-2001 to 09-FEB-2001 for a very low hemoglobin count of 7. The patient was given three pints of blood. The patient was rehospitalized from 11-FEB-2001 to 13-FEB-2001 for a low hemoglobin and

(Continued on Additional Page)

6. Relevant tests/laboratory data, including dates

Refer to Additional Page

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

CONCURRENT CONDITIONS: cat allergy; dog allergy; dust allergy; grass allergy; peptic ulcer

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
1 TAB SINGULAIR 10 mg
2 aspirin Unk
2. Dose, frequency & route used
1 10 mg/DAILY/PO
2 Unk/Unk/Unk
3. Therapy dates (from/to) (if unknown, give duration)
1 Unk - Cont
2 01/??/01 - Unk
4. Diagnosis for use (indication)
1 asthma
2 Unknown
5. Event abated after use stopped? (if dose reduced)
1 yes [] no [] N/A [X] Unk []
2 yes [] no [] N/A [] Unk [X]
6. Lot # (if known)
7. Exp date (if known)
8. Event reappeared after reintroduction?
1 yes [] no [] N/A [X] Unk []
2 yes [] no [] N/A [] Unk [X]
9. NDC # - for product problems only (if known)
Unknown
10. Concomitant medical products and therapy dates (excluded treatment of event)
ADVIL Unk -Unk
PROTONIX Unk -Unk
(Continued on Additional Page)

G. All manufacturers

1. Contact office - name/address
Merck Human Health Division
Merck & Co., Inc.
P.O. Box 4
West Point, PA 19486-0004
ATTN: Worldwide Product Safety
2. Phone Number
(610)397-2416
3. Report source (check all that apply)
[] foreign
[] study
[] literature
[X] consumer
[X] health professional
[] user facility
[] company representative
[] distributor
[] other:
4. Date received by manufacturer (mo/day/yr) 03/13/01
5. (A)NDA # 20829
IND #
PLA #
pre-1938 [] yes
OTC product [] yes
9. Mfr. report number
WAES 01030805

8. Adverse event term(s)
HEMOGLOBIN DECREASED; DUODENAL ULCER; FALLING; SHOULDER PAIN; GASTROINTESTINAL BLEEDING

E. Initial reporter
1. Name, address & phone #
[redacted]
[redacted]
[redacted]
[redacted]
MAR 23 2001

2. Health professional? [X] YES [] NO
3. Occupation M.D.
4. Initial reporter also sent report to FDA. [] yes [] no [X] no

FDA Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

MAR 23 2001



5. Describe event or problem

received two more pints of blood. The consumer also reported that a small duodenal ulcer was found. On 07-MAR-2001 the patient's hemoglobin was 11.1. The consumer added that all of these effects only occurred when he began to take "a lot of aspirin". The patient's physician stated that there was no indication that therapy with montelukast sodium was related to the gastrointestinal bleeding and that the patient had been using ibuprofen "by the bottle" for pain relief. At the time of this report therapy with montelukast sodium continued.

No further details are expected.

6. Relevant tests/laboratory data, including dates

LABORATORY RESULTS

Tests

Tests	Date	Value	Unit	Normal Range
hemoglobin	01/??/01	14.5		
hemoglobin	02/07/01	7		
hemoglobin	03/07/01	11.1		

C. Suspect medication(s)

10. Concomitant medical products and therapy dates (exclude treatment of event)

ZESTRIL	Unk - Unk
ZOCOR	Unk - Unk
iron (unspecified)	Unk - Unk

DSS

MAR 23 2001

MAR 23 2001

Individual Safety Report



3690601-0-00-01

OLUNTARY reporting
by health professionals of adverse
events and product problems

Form Approved OMB No. 0910-0291 Expires 12/31/04
See FIMB statement on reverse

FDA Use Only H-Pes

Trace Unit
Sequence # 1

140052

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 1

A. Patient information

1. Patient identifier 6794 In confidence	2. Age at time of event: 61 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 160 lbs or kgs
--	--	---	-----------------------------------

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects malfunctions)

2. Outcomes attributed to adverse event (check all that apply):
 death
 life-threatening
 hospitalization - initial or prolonged
 disability
 congenital anomaly
 required intervention to prevent permanent impairment/damage
 other

3. Date of event (month/year): 11/6/00
 4. Date of this report (month/year): 1/20/01

5. Describe event or problem:
 60 y/o w/m had hematemesis & weakness because of aspirin induced gastritis.

6. Relevant tests/laboratory data, including dates:
 11/7/00 WBC = 13.9
 Hgb = 8.7
 BUN = 39
 K = 5.3
 Glucose = 100

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):
 history of hypertension, coronary artery disease, DSD
 CTN140052

Mail to: MEDWATCH
 5600 Fishers Lane
 Rockville, MD 20852-9787
 or FAX to:
 1-800-FDA-0178



FDA Form 3500 (6/99)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

C. Suspect medication(s)

1. Name (give date or strength & unit/dose or, if known):
 #1 aspirin
 #2

2. Dose, frequency & route used:
 #1 81 mg
 #2

3. Therapy dates (if unknown, give dates):
 #1 8/00 - 11/00
 #2

4. Diagnosis for use (indication):
 #1 CAD prophylaxis
 #2

5. Event abated after use stopped or dose reduced:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

6. Lot # (if known):
 #1
 #2

7. Exp. date (if known):
 #1
 #2

8. Event reappeared after reintroduction:
 #1 yes no doesn't apply
 #2 yes no doesn't apply

9. NDC # (for product problems only):
 #1
 #2

10. Concomitant medical products and therapy dates (exclude treatment of event):
 aspirin, Lipid (8/00 - 11/00)

D. Suspect medical device

1. Brand name:
 2. Type of device:
 3. Manufacturer name & address:
 4. Operator of device:
 health professional
 lay user/patient
 other:
 5. Expiration date (month/year):
 6. model #:
 MAR 27 2000
 7. If implanted, give date (month/year):
 8. If explanted, give date (month/year):
 9. Device available for evaluation? (Do not send to FDA):
 yes no returned to manufacturer on (month/year):
 10. Concomitant medical products and therapy dates (exclude treatment of event):

E. Reporter (see confidentiality section on back)

1. Name, address & phone #:
 W.G. (Bill) Hefner VAMC (111)
 1601 Brenner Avenue
 Salisbury, NC 28144
 2. Health professional? yes no
 3. Occupation:
 4. Also reported to:
 manufacturer
 user facility
 distributor
 5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



3690604-6-00-01

VOLUNTARY reporting
by health professionals of adverse
events and product problems

FDA Use Only H-Pad

Image unit
sequence # **140058**

Page _____ of _____

A. Patient information

1. Patient identifier [redacted] 9110 In confidence	2. Age at time of event: 47 or Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 160 lbs or _____ kgs
--	---	---	--

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects, malfunctions)

2. Outcomes attributed to adverse event (check all that apply):

<input type="checkbox"/> death	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization or medical prolongation	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (m/d/yyyy) **12/29/00**

4. Date of this report (m/d/yyyy) **2/20/01**

5. Describe event or problem:

*47 y/o w/m with
retinal bleeding;
pt. has been
taking aspirin
for CHD prophylaxis.*

6. Relevant tests/laboratory data, including dates:

*12/29/00: BUN=17
Mg=1.42
Creat=0.6*

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):

*coronary artery disease,
hypertension, GERD*

C. Suspect medication(s)

1. Name (give label strength & mfr/labeler, if known):

#1 *aspirin*

#2 _____

2. Dose, frequency & route used:

#1 *81 mg*

#2 _____

3. Therapy dates, if unknown, give duration (m/d/yyyy - m/d/yyyy):

#1 *6/00 - 12/00*

#2 _____

4. Diagnosis for use (indication):

#1 *CHD prophylaxis*

#2 _____

5. Event abated after use stopped or dose reduced:

#1 yes no does not apply

#2 yes no does not apply

6. Event reappeared after reintroduction:

#1 yes no does not apply

#2 yes no does not apply

7. Lot # (if known):

#1 _____

#2 _____

8. Exp. date (if known):

#1 _____

#2 _____

9. NDC # (for product problems only):

#1 _____

#2 _____

10. Concomitant medical products and therapy dates (exclude treatment of event):

*Klonopin, tramadol,
aspirin, aspirin
antibiotics (6/00-12/00)*

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

RECEIVED
MAR 27 2001

4. Operator of device:

health professional
 lay user/patient
 other: _____

5. Expiration date (m/d/yyyy)

6. model # **MEDWATCH CTU**

7. If implanted, give date (m/d/yyyy)

8. If explanted, give date (m/d/yyyy)

9. Device available for evaluation? (Do not send to FDA)

yes no returned to manufacturer on _____ (m/d/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted]

W.G. (Bill) Hefner VAMC (111)
1601 Brenner Avenue
Salisbury, NC 28144

2. Health professional? yes no

3. Occupation

4. Also reported to:

manufacturer
 user facility
 distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box.



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

CTU140058



3690634-4-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

FDA Use Only

Triage unit sequence # **190097**

A. Patient information

1. Patient identifier 18053140 In confidence	2. Age at time of event: 64 Years or _____ Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ lbs or 82.5 kgs
--	--	---	---

B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event **12/06/2000** (mm/dd/yyyy)

4. Date of this report **03/23/2001** (mm/dd/yyyy)

5. Describe event or problem
patient admitted with "coffee-ground" emesis, upper GI bleed.

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Aspirin / /	3. Therapy dates (if unknown, give duration) #1 From - To (or best estimate)
2. Dose/Frequency/Route used #1 / /	5. Event abated after use stopped or dose reduced #1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
4. Diagnosis for use (separate indications with commas) #1	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known) #1	7. Exp. date (if known) #1
9. NDC # (for product problems only) -	10. Concomitant medical products and therapy dates (exclude treatment of event) pepcid, norvasc, lasix, hctz, risperdal, dilantin, clonidine, phenobarbital, effexor, potassium

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

4. Operator of device
 health professional
 lay user/patient
 other: _____

5. Expiration date (mm/dd/yyyy)

6. model # _____
catalog # _____
serial # _____
lot # _____
other # _____

7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
 yes no returned to manufacturer on (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name _____ phone # _____

United States

2. Health professional? yes no

3. Occupation Pharmacist

4. Also reported to
 manufacturer
 user facility
 distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box.

CTV 40097



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787
or FAX to:
1-800-FDA-0178



3690665-4-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

FDA Use Only

Triage unit sequence #	14013
------------------------	-------

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
-------------------------------------	---	---	---

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	
3. Date of event 01/15/2001 (mm/dd/yyyy)	4. Date of this report 03/26/2001 (mm/dd/yyyy)

5. Describe event or problem

Pt presented to emergency dept with c/o coffee-ground emesis and melanotic stool two days prior. Also reported nausea, abdominal pain, dizziness, and orthostasis. Had reported to local ER and was subsequently transferred here. NG lavage was negative, but rectal examination was heme positive. Pt admitted for GI workup. Was discovered to have gastric ulcer suspicious for malignancy and duodenal ulcer as well.

6. Relevant tests/laboratory data, including dates

RECEIVED
MAR 27 2001
MEDWATCH CTU

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

EtOH dependency

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)		
#1 Ibuprofen / 400 mg /		
#2 EC ASA / 325 mg /		
2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)	
#1 400 mg / TID / Oral	#1 From - To (or best estimate)	
#2 325 mg / daily / Oral	#2 -	
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced	
#1	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#2	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2	#2	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		
- - -		
10. Concomitant medical products and therapy dates (exclude treatment of event)		
atenolol docusate glyburide lisinopril prazosin psyllium		

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other
6. model #	5. Expiration date (mm/dd/yyyy)
catalog #	7. If implanted, give date (mm/dd/yyyy)
serial #	8. If explanted, give date (mm/dd/yyyy)
lot #	
other #	
9. Device available for evaluation? (Do not send device to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)

1. Name	phone #
[redacted]	
VA Pittsburgh Healthcare System -132M-E-; 7180 Highland Drive Pittsburgh Pennsylvania 15206 United States Mario.Dinardo@med.va.gov	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist
4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>	



Mail to: **Washington**
5600 Fishers Lane
Rockville, MD 20852-9787

or-FAX to:
1-800-FDA-0178

CTU 14013



3692506-8-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
by health professionals of adverse
events and product problems
Internet Submission - Page 1

Form Approved OMB No. 0910-0291 Expires: 12/31/00
See OMB statement on reverse

FDA Use Only

Triage unit sequence #	140281
------------------------	--------

A. Patient information

1. Patient identifier LOG#4037 In confidence	2. Age at time of event: 82 Years Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 130 lbs or kgs
--	---	---	-----------------------------------

B. Adverse event or product problem

1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	
<input type="checkbox"/> death (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
<input type="checkbox"/> other: _____	

3. Date of event (mm/dd/yyyy) 10/11/2000	4. Date of this report (mm/dd/yyyy) 03/28/2001
---	---

5. Describe event or problem

Erosive, diffuse gastritis -by gastroscopy-, melena, anemia, orthostasis attributed to Vioxx and ASA by GI consult. Acute renal failure attributed by renal consult to decreased cardiac output, volume depletion, ischemic cardiomyopathy, anemia and/or NSAID use [only on Vioxx and daily ASA] By discharge SrCr 1.7 BUN 31 October 19th, 2000

MAR 29 2001

6. Relevant tests/laboratory data, including dates

Admission HGB 8.7% HCT 27.1% SrCr 3.6 BUN 55

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

s/p CABG, PTCA, AMI, HTN, Hx -April 2000- ARF secondary to IV contrast at that time SrCr 1.6 BUN 44 but returned to 'almost normal' at discharge in April 2000.

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler)	
#1 Vioxx / 12.5mg /	
#2 aspirin / 325mg /	
2. Dose/Frequency/Route used	3. Therapy dates (if unknown, give duration)
#1 12.5 mg / once daily / Oral	#1 From 01/01/2000 - To (or best estimate) 10/11/2000
#2 325 mg / once daily / Oral	#2 01/01/2000 - 10/11/2000
4. Diagnosis for use (separate indications with commas)	5. Event abated after use stopped or dose reduced
#1 Unknown	#1 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 s/p AMI, ICM	#2 <input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1	#1
#2	#2
9. NDC # (for product problems only)	8. Event reappeared after reintroduction
-	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
10. Concomitant medical products and therapy dates (exclude treatment of event)	
Lanoxin, KCL, Plavix, MVI, Isordil	

D. Suspect medical device

1. Brand name	
2. Type of device	
3. Manufacturer name & address	4. Operator of device
	<input type="checkbox"/> health professional
	<input type="checkbox"/> lay user/patient
	<input type="checkbox"/> other: _____
6. model #	5. Expiration date (mm/dd/yyyy)
catalog #	7. If implanted, give date (mm/dd/yyyy)
serial #	8. If explanted, give date (mm/dd/yyyy)
lot #	
other #	
9. Device available for evaluation? (Do not send device to FDA)	
<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Reporter (see confidentiality section on back)

1. Name	phone
[redacted]	[redacted]
[redacted] Ave	
[redacted]	
United States	
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist
4. Also reported to <input type="checkbox"/> manufacturer <input checked="" type="checkbox"/> user facility <input type="checkbox"/> distributor	
5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input type="checkbox"/>	



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

CTU 140281



3695032-5-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM



Approved by FDA on 12/02/93

Mfr report #	A009315
UF/Dist report #	
FDA Use Only	

*+ indicates item continued

A. Patient Information				C. Suspect medication(s)			
1. Patient Identifier [redacted] in confidence		2. Age at time of event: UNKNOWN or Date of Birth: [redacted]		3. Sex <input checked="" type="checkbox"/> Female <input type="checkbox"/> Male		4. Weight 175.0lbs or [redacted] kgs	
B. Adverse event or product problem				1. Name (give labeled strength & mfr/labeler, if known)			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g. defects/malfunctions)				# 1 CARDURA		Cont.	
2. Outcomes attributed to adverse event (Check all that apply)				2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration) from/to (or best est dates)	
<input type="checkbox"/> death (mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged				<input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input type="checkbox"/> required intervention to prevent <input type="checkbox"/> permanent impairment/damage <input checked="" type="checkbox"/> other: NOT SERIOUS		# 1 --/95 - PRESENT	
3. Date of event --/95 (mo/day/yr)		4. Date of this report 03/28/01 (mo/day/yr)		# 2 10.00 MG TOTAL DAILY ORAL		# 2 --/95 - PRESENT	
5. Describe event or problem				4. Diagnosis for use (indications)		5. Event abated after use stopped or dose reduced	
THIS CURRENTLY 60 YEAR OLD FEMALE CONSUMER REPORTS THAT IN 95 SHE STARTED TAKING CARDURA (DOXAZOSIN) 16MG DAILY, NORVASC (AMLODIPINE) 10MG DAILY, AND AN UNSPECIFIED DIURETIC DAILY FOR HIGH BLOOD PRESSURE. LATER IN 95, SHE EXPERIENCED URINE LEAKAGE. IN 96 THE DIURETIC WAS DISCONTINUED BECAUSE HER BLOOD PRESSURE IMPROVED. AFTER THE DIURETIC WAS DISCONTINUED, THE URINE LEAKAGE IMPROVED. AT AN UNKNOWN TIME, THE CARDURA WAS DECREASED TO 6MG DAILY FOR UNSPECIFIED REASON. AT AN UNKNOWN TIME, SHE BEGAN TAKING "BABY" ASPIRIN. IN FEB00 SHE WAS DIAGNOSED WITH 2 PEPTIC ULCERS. IN FEB00, DUE TO THE PEPTIC ULCERS, THE ASPIRIN WAS DISCONTINUED AND SHE WAS PRESCRIBED PRILOSEC (OMEPRAZOLE). AS OF 15MAR00 SHE STATES SHE STILL HAS URINE LEAKAGE BUT ONLY WHEN SHE SNEEZES OR COUGHS. AN ENDOSCOPY IS SCHEDULED FOR MAY00 TO CHECK THE ULCERS.				# 1 HIGH BLOOD PRESSURE # 2 HIGH BLOOD PRESSURE		# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply # 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Relevant tests/laboratory data, including dates				6. Lot # (if known)		7. Exp. date (if known)	
UNKNOWN				# 1 UNKNOWN # 2 UNKNOWN		# 1 UNKNOWN # 2 UNKNOWN	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.)				9. NDC # - for product problems only (if known)		8. Event reappeared after reintroduction	
NONE				N/A		# 1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply # 2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
				10. Concomitant medical products and therapy dates (exclude treatment of event)			
				NONE			
G. All manufacturers							
1. Contact office - name/address (& mfring site for devices)				2. Phone number			
PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42 STREET NEW YORK, N.Y. 10017 U.S.A.				212-573-3129			
4. Date received by manufacturer (mo/day/yr)				3. Report source (check all that apply)			
03/15/00				<input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" type="checkbox"/> consumer <input type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
6. If IND, protocol #				5. (A) NDA # NDA #19-588 IND # PLA #			
N/A				pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes			
7. Type of report (check all that apply)				8. Adverse event term(s)			
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-Day <input checked="" type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up #				PEPTIC ULCER URINARY TRACT DISORDER			
9. Mfr. report number							
A009315							
E. Initial reporter							
1. Name, address & phone #							
[redacted] AVE. [redacted] Tel. [redacted]							
2. Health professional?		3. Occupation		4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		HOUSEWIFE		<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> link			



106 Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report



3695032-5-00-02

Approved by FDA on 12/02/93

Mfr report #	A009315
UF/Dist report #	
FDA Use Only	

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) # 3 UNSPECIFIED DIURETIC # 4 BABY ASPIRIN	
2. Dose, frequency & route used # 3 DAILY ORAL # 4 DAILY ORAL	3. Therapy dates (if unknown, give duration from/to (or best estimates)) # 3 --/95 - PRESENT # 4 UNKNOWN - 02/--00
4. Diagnosis for use (indications) # 3 HIGH BLOOD PRESSURE # 4 INDICATION UNKNOWN	5. Event abated after use stopped or dose reduced # 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply UNKNOWN # 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known) # 3 UNKNOWN # 4 UNKNOWN	7. Exp. date (if known) # 3 UNKNOWN # 4 UNKNOWN
8. Event reappeared after reintroduction # 3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply # 4 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	