

Individual Safety Report



668468-6-00-01

OLUNTARY reporting
 lth professionals of adverse
 its and product problems

Form Approved: CMB No. 0919-0291 Expires: 12-31-00
 See OMB statement on reverse

FDA Use Only

Triage unit sequence # **138124**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Internet Submission - Page 1

A. Patient information

1. Patient identifier [REDACTED]	2. Age at time of event: 42 Years or Date of birth: 02/10/1959	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight 201 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 (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 checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (mm/dd/yyyy) **02/15/2001**

4. Date of this report (mm/dd/yyyy) **02/16/2001**

5. Describe event or problem

My husband caught a cold and used NyQuil, after four days of use, he became pale and vomiting blood. He was rushed to the hospital and found to have Tylenol poisoning from the NyQuil use. Since this diagnosis he had to be put into ICU unit and has since received 10 pints of blood and other drugs to control the bleeding. As of yesterday he spent 4+ days in the ICU, and has since been removed to another unit for close observation. The results being not much of a life considering the damage done to his stomach due to the liver failing from the use of NyQuil. Now according to the ER personnel this is not the first case of this type involving this particular product! Why are there not more warnings out to the consumers regarding adverse reactions to the use of this product?

6. Relevant tests/laboratory data, including dates

[Empty field for tests/laboratory data]

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

My husband has had some stomach problems in the past and nowhere on the bottle of NyQuil that if you have ever had stomach problems DO NOT USE THIS PRODUCT!!!

C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Vicks NyQuil / 295ml / Proctor & Gamble	#2
2. Dose/Frequency/Route used #1 2tbsp / 30ml / Subconjunctival	3. Therapy dates (if unknown, give duration, From To (or best estimate)) #1
#2	#2
4. Diagnosis for use (separate indications with commas) #1	5. Event abated after use stopped or dose reduce? #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" 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) #1 235RH	7. Exp. date (if known) #1 01/31/2002
#2	#2
9. NDC # (for product problems only) -	8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
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 #
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 [REDACTED] phone # [REDACTED]

2. Health professional?
 yes no

3. Occupation
 Consumer/Non-Health Prof

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
 FEB 22 2001



Mail to: MEDWATCH
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 or FAX to:
 1-800-FDA-0178

CTU138124