

Individual Safety Report



3662337-3-00-01

r VOLUNTARY reporting
 alth professions of adverse
 nts and product problems

FDA Use only

137227

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [Redacted]	2. Age at time of event: <u>37</u>	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight <u>148</u> lbs
In confidence	Date of birth <u>4-5-63</u>		

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 <u>1/3/00</u>	4. Date of this report <u>1/30/01</u>
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Describe event or problem

102/79 Acetaminophen overdose: 37 year old female with history of gastric bypass, was admitted 10/3 after taking 20 tablets of regular strength Tylenol for a "severe headache". Acetaminophen level was 492 and urine drug screen positive for alcohol 119mg/dl, benzodiazepines, and salicylate. She was admitted to ICU and given Mucomyst. She had early changes in liver function and consults were made for endocrine, psych, and transplant, GI. Psych consult recommended lithium. She was discharged home 10/7. (Probable 2)

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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 <u>Acetaminophen</u>	
#2 <u> </u>	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration)
#1 <u>325mg X10</u>	from/to (or best estimate): #1 <u>10/3/00 @ 0500</u>
#2 <u> </u>	#2 <u> </u>
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 <u> </u>	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2 <u> </u>	#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 <u> </u>	#1 <u> </u>
#2 <u> </u>	#2 <u> </u>
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 (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	4. Operator of device
RECEIVED	<input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
5. Expiration date	6. If implanted, give date
FEB 08 2001	
7. If explanted, give date	8. If explanted, give date
model #	
MEDWATCH CTU	
catalog #	
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	
10. Concomitant medical products and therapy dates (exclude treatment of event)	

E. Initial reporter

1. Name, address & phone # [Redacted]		
2. Health professional?	3. Occupation	4. Also reported to
	Pharmacist	<input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor