



For use by user-facilities,
 stores and manufacturers for
MANDATORY reporting

Approved by FDA on 10/29/93

Mfr report #	981007-107013855
UF/Dist report #	
FDA Use Only	

PRODUCTS' REPORTING PROGRAM

Page 1 of 2

A. Patient information			
1. Patient identifier UNKNOWN In confidence	2. Age at time of event: 39 Year(s) Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or UNK ____ 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 checked="" 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 UNK (mo/day/yr)	4. Date of this report 11/05/98 (mo/day/yr)		
5. Describe event or problem			
<p>Report published in American Journal of Emergency Medicine 16(5), 1997 Annual Report of Poison Control Centers TESS: pp.443-497 (case 215) of a 39 year old, sex unspecified, who ingested acetaminophen and acetaminophen with codeine for an unknown reason resulting in death. Chronicity was unknown. Additional information has been requested.</p> <p>Follow-up information received 02-NOV-98: This female patient had taken an unknown quantity of acetaminophen and 10 TYLENOL With Codeine #3 tablets. She was seen in the emergency department (ED) 24 hours later with nausea and vomiting, and discharged. An additional 24 hours later, she was found on the floor and taken to the ED where she was brunded, acidotic, hypotensive and in kidney failure. Her acetaminophen level was 68 ug/mL, SGOT was >9,000 U/L, prothrombin time (PT) >100 seconds. GGT was within normal limits and CK was 300 U/L. She had an increased myoglobin. Bicarbonate was 8 mEq/L, creatinine 23 mg/dL, there was no osmolar gap. The patient was ventilated, treated with IV fluids and acetylcysteine by nasogastric (NG) tube every 4 hours. There was some blood in the NG tube, with some bleeding from the mouth and nose. There was no urine output. She was given 4 units of packed cells and 6 units of fresh frozen plasma. She opened her eyes occasionally, but not on command. Her cardiac enzymes were elevated. Her blood gas pH was 7.28. She was in sinus tachycardia with no sign of</p> <p style="text-align: right;">(Cont.)</p>			
6. Relevant tests/laboratory data, including dates			
Blood concentration- 68 ug/mL of acetaminophen.			
<p>Follow-up information received 02-NOV-98: Day 1 SGOT >9,000 U/L, PT >100 seconds, GGT within normal limits, CPK 300 U/L, blood gas pH 7.28</p> <p>Day 2 PT 30 seconds, SGOT 9500 U/L, BUN 30 mg/dL, creatinine 3.2 mg/dL</p> <p>Day 3 INR 3-4, heart rate 160, PT 65.2 seconds, PTT 6-33 seconds, BUN 8 mg/dL, creatinine 2.9 mg/dL, total bilirubin 8.6 mg/dL, AST 6500 U/L</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
Follow-up information received 02-NOV-98: pancreatitis, alcoholism			

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known)			
#1 TYLENOL WITH CODEINE #3 TABLETS (ACETAMINOPHEN & CODEINE)			
#2 ACETAMINOPHEN			
2. Dose, frequency & route used		3. Therapy dates (if unknown, give duration (from/to or best estimate))	
#1 10 TAB, Unknown, ORAL		#1 Unknown	
#2 Unknown, Unknown, Unknown		#2 Unknown	
4. Diagnosis for use (indication)		5. Event abated after use stopped or dose reduced	
#1 unknown		#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 checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)		7. Exp. date (if known)	
#1 UNK		#1 UNK	
#2 UNK		#2 UNK	
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 (if known)			
NA			
10. Concomitant medical products and therapy dates (exclude treatment of event)			
1) UNKNOWN ??/??/?? - ??/??/??			
G. All manufacturers			
1. Contact office - name/address (& mfring site for devices)		2. Phone number	
R. W. JOHNSON PHARM. RESEARCH INSTITUTE DIV. OF ORTHO PHARMACEUTICAL CORPORATION ROUTE 202, P.O. BOX 300 RARITAN NJ 08869-0602		(908) 704-4600	
(Informing unit)		3. Report source (check all that apply)	
		<input type="checkbox"/> foreign	
		<input type="checkbox"/> study	
		<input checked="" type="checkbox"/> literature	
		<input type="checkbox"/> consumer	
		<input checked="" 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 #	
11/02/98		85-055	
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		8. Adverse event term(s)	
<input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # 1		1) ACIDOSIS	
		2) RENAL FAILURE ACUTE	
		3) TACHYCARDIA	
		4) SGOT INCREASED	
		5) PROTHROMBIN DECREASED	
		6) CREATINE PHOSPHOKINASE INCREASED	
		7) NFN INCREASED	
		(Cont.)	
E. Initial reporter			
1. Name, address & phone #			
TOBY L. LITOVITZ, M.D. AMERICAN ASSOC OF POISON CONTROL CENTERS 3201 NEW MEXICO AVENUE, SUITE 310 WASHINGTON DC 20016 Phone #: 202-362-3867			
2. Health professional?		3. Occupation	4. Initial reporter also sent report to FDA
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		Physician	<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.



3155752-8-00-02

E

Continuation Sheet for FDA-3500A Form

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Page 2 of 2**B.5 Describe event or problem (Cont...)**

ischemia. She was normotensive. On day 2 her PT was 30 seconds after 10 units of platelets, SGOT was 9500 U/L. She was on dialysis, BUN 30 mg/dL, creatinine 3.2 mg/dL and treatment with acetylcysteine continued. Hematocrit was stable and lung function decreased. She was depending primarily on the ventilator and not responsive. On day 3 she was still on the ventilator and the amount of oxygen needed had decreased. Her blood pressure was maintained with norepinephrine bitartrate. INR was 3-4 with fresh frozen plasma, 4 units every 8-12 hours. Heart rate 160. Dialysis and treatment with acetylcysteine continued. PT 65.2 seconds, PTT 6-33 seconds, BUN 8 mg/dL, creatinine 2.9 mg/dL, total bilirubin 8.6 mg/dL, AST 6500 U/L. DIC screen results, some positive parts, some not. On day 4 there was no change in condition or treatment. On day 5 she was still not responsive. On day 9 the patient received a maximum amount of pressors which did not help. She expired approximately 0600. The patient had a history of pancreatitis and alcoholism.

G. All manufacturers (Cont...)**G.8 Adverse event term(s)**

- 8) BUN INCREASED
- 9) BILIRUBINAEMIA
- 10) THERAPEUTIC RESPONSE INCREASED
- 11) COMA
- 12) NAUSEA
- 13) VOMITING
- 14) STUPOR
- 15) HYPOTENSION
- 16) RESPIRATORY DEPRESSION

Source of report (Literature)

Title	: 1997 ANNUAL REPORT OF THE AMERICAN ASSOCIATION OF POISON CONTROL CENTERS TOXIC EXPOSURE SURVEILLANCE SYSTEM
Author	: TOBY L. LITOVITZ, ET AL
Year	: 1998
Edition	: 16(5)
Journal Title	: AMERICAN JOURNAL OF EMERGENCY MEDICINE
Page No.	: 443 To 497

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