



McNeil Consumer Healthcare
McNeil Consumer Healthcare
Fort Washington, PA 19034-2299

Approved by FDA on 11/15/93
Mfr report #
UF/Dist report #
FDA use only

Page ___ of ___

A. Patient information				C. Suspect medication(s)			
1. Patient identifier [redacted]	2. Age at time of event: 34 yrs Date of birth:	3. Sex () female (X) male	4. Weight 140 lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Extra Strength TYLENOL PM product #2		2. Dose, frequency & route used #1 unknown dose, po #2	
B. Adverse event or product problem				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 accidental overdose #2		8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A	
2. Outcomes attributed to adverse event (check all that apply) (x) death (mo/day/yr) 6/6/00 () life-threatening () hospitalization - initial or prolonged () other: none				6. Lot # (if known) #1 unknown #2		7. Exp. date (if known) #1 unknown #2	
3. Date of event (mo/day/yr) 6/6/00		4. Date of this report (mo/day/yr) 09/06/00		9. NDC # - for product problems only (if known)			
5. Describe event or problem Detective report of DEATH allegedly associated w/the use of one of our Extra Strength TYLENOL® PM products in a 34 year old pt w/ hx of bipolar disorder. According to detective, the male had been complaining of nonspecific pains for a few wks prior to his death & began taking an unknown dose of an Extra Strength TYLENOL® PM product. Four to 5 days prior to his death, the male reportedly went to a clinic & rec'd ibuprofen 800 mg for pain. On 6/4/00, the male was last seen alive, but was lethargic (SOMNOLENCE). On 6/6/00, his body was found in the bathroom w/ foam around his mouth & nose (REACTION UNEVALUABLE). Detective reports an empty bottle of Extra Strength TYLENOL PM was found in a trash can at the scene. No note was found, nor was any indication of suicide found at the scene. Autopsy revealed APAP level=499.7 mg/L & DPH level=5,440 ng/L (overdose). Addl info rec'd 9/5/00: Final autopsy report indicates pt had body ache a few days previous & was treated w/ pain medication. He was also on NARDIL®. Pt found dead 6/6/00. Internal exam (See Sect B7)				10. Concomitant medical products and therapy dates (exclude treatment of event) NARDIL®, ibuprofen (Sect B6 cont): of liver showed advanced PM autolysis & marked vascular congestion (Sect B7 Cont): cardiac arrest (HEART ARREST), due to drug OD (Tylenol PM). Manner of death listed as accident (ACCIDENTAL OVERDOSE).			
6. Relevant tests/laboratory data, including dates 6/13/00 (20:18) APAP level=499.7mg/L, DPH level=5,440ng/mL, ETOH 0.058 G/dL; blood=(+) for APAP, DPH, caffeine; urine=(+) for DPH & metab, doxylamine & metab, dextromethorphan, caffeine, nicotine & metab, APAP; micro exam (See Sect C10)				G. All manufacturers			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) depression, seizure disorder, bipolar disorder, hx of alcohol abuse tx'd by AA, no ETOH reportedly in last 5 or 6 yrs (Sect B5 cont): showed pt had mild anthracosis in lung (LUNG FIBROSIS) & moderate pulmonary edema (LUNG EDEMA). Anatomical dx=1) moderate pulmonary congestion, bilateral, & 2.) malnutrition, mild.COD listed as pulmonary(See Sect C10)				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303	
				4. Date received by manufacturer (mo/day/yr) 09/05/00		3. Report source (check all that apply) () foreign () study () literature () consumer () health professional (X) professional () user facility () company representative () distributor () other:	
				5. (IA) NDA # SEP 15 2000			
				6. If IND, protocol #		IND # PLA # pre-1938 () Yes OTC product (X) Yes	
				7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up #, 1		8. Adverse event term(s) DEATH SOMNOLENCE REACTION UNEVAL FIBROSIS LUNG EDEMA LUNG HEART ARREST OVERDOSE ACCID	
				9. Mfr. report number 1397072A			
				E. Initial reporter			
				1. Name, address & phone # [redacted] MD Associate Medical Examiner, District [redacted] [redacted] Hospital			
2. Health professional? (X) Yes () No		3. Occupation coroner		4. Initial reporter also sent report to FDA () Yes () No (X) 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.