



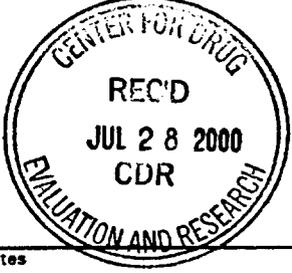
McNeil
Consumer Healthcare
McNeil Consumer Healthcare
Washington, PA 19034-2299

Approved by FDA on 11/15/93

Mfr report #
UF/Dev report #
FDA use only

Page ___ of ___

A. Patient information				C. Suspect medication(s)			
1. Patient identifier 30922499 In confidence	2. Age at time of event: 34 yrs or Date of birth: [redacted]	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified TYLENOL product #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 unknown dose, po #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 6/27/00; 1 day #2	
				4. Diagnosis for use (indication) #1 unknown #2		5. Event abated after use stopped or dose reduced #1 () Yes (X) No () N/A #2 () Yes () No () N/A	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				6. Lot # (if known) #1 Unknown #2		7. Exp. date (if known) #1 Unknown #2	
2. Outcomes attributed to adverse event (check all that apply) () death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly (X) required intervention to prevent permanent impairment/damage () other:				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No () N/A			
3. Date of event 6/27/00 (mo/day/yr)		4. Date of this report 07/25/00 (mo/day/yr)		9. NDC # - for product problems only (if known)			
5. Describe event or problem Pharmacist report from Drug Information Service received via fax from affiliate of abnormal liver function tests (LIVER FUNCTION TESTS ABNORMAL), elevated intracranial pressure (INTRACRANIAL HYPERTENSION), and HEPATIC FAILURE allegedly associated with the use of an unspecified TYLENOL® product. According to report, on 6/27/00, pt was admitted to Acute Care Medical GI unit with abnormal liver function tests. On 6/28/00, at an unspecified interval after ingestion, acetaminophen level=31.6. On 6/30/00, pt was placed on ICP monitor due to elevated intracranial pressure related to hepatic failure reportedly due to TYLENOL ingestion. Pt was discharged 7/13/00. No further information was provided.				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown			
6. Relevant tests/laboratory data, including dates 6/28/00: acetaminophen level=31.6, pH=7.19, INR=2.3, AST=6002, ALT=6736, ALK=147, albumin=2.6				G. All manufacturers			
				1. Contact office - name/address (& mfg site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) unknown				4. Date received by manufacturer (mo/day/yr) 07/17/00		5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes	
				6. If IND, protocol #		7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic (X) Initial () follow-up #	
8. DSS JUL 31 2000				9. Mfr. report number 1400067A			
				E. Initial reporter			
Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.				1. Name, address & phone # [redacted] Box [redacted] Drive [redacted]			
				2. Health professional? (X) Yes () No		3. Occupation Pharmacist	



JUL 28 2000