



McNEIL CONSUMER PRODUCTS COMPANY
FORT WASHINGTON, PA 19034

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page ____ of ____

Mfr report #
UF/Dist report #
FDA use only

A. Patient information				C. Suspect medication(s)			
1. Patient identifier [redacted] In confidence	2. Age at time of event: 41 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 Extra Strength TYLENOL Caplets #2		2. Dose, frequency & route used #1 unknown dose, tid, po #2	
B. Adverse event or product problem				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 1981-1989; 9 years #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 pain and headache #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) () death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage () other:				6. Lot # (if known) #1 unknown #2		7. Exp. date (if known) #1 unknown #2	
3. Date of event (mo/day/yr) 4/10/89		4. Date of this report (mo/day/yr) 02/15/99		9. NDC # - for product problems only (if known)			
5. Describe event or problem <p>Consumer alleges that use of Extra Strength TYLENOL® acetaminophen Caplets was associated w/HEPATOMEGALY (swollen liver). Consumer was taking 500 mg qd-bid for pain & headaches from 1981-1989. Addl info rec'd 7/30/98 & 11/23/98: Consumer's written report from 7/30/98 indicates she was diagnosed w/liver failure in 1989 from using TYLENOL. On occasion, she has liver pain. MD note from consumer on 7/30/98 indicates liver problems. On 5/2/89, she was hospitalized w/CC of right sided ADOMINAL PAIN & later the same day, she left hosp AMA. Med data form rec'd 11/23/98 indicates she was taking unknown dose of Extra Strength TYLENOL tid for pain in RUQ & started to have problems on 4/10/89. Addl info rec'd 2/12/99 & 2/18/99: MD rec indicate pt w/H/O ETOH use has NAUSEA & 6 mo H/O episodes of RUQ Abd pain. Pt went to ER on 4/9/89 & abnormal LFT's noted. Pt went home & returned to ER next day. On PE, liver noted to be enlarged & mildly tender. MD's IMP: pt has some liver disease. LFT's appear to high for alcoholic hepatitis & she may have a viral (See Sec C10)</p>				10. Concomitant medical products and therapy dates (exclude treatment of event) PREMARIN® & "a lot of ADVIL"; (Sec B5 cont): HEPATITIS or FATTY LIVER. Other liver diseases should be considered. Use of TYLENOL not documented in consultation report. (Sec B7 cont):cholecystectomy (LFT's reportedly normal at that time)			
6. Relevant tests/laboratory data, including dates 4/10/89 in ER: AP=149, bili=normal, SGOT=608, SGTP=538, Hgb=12.1, WBC= 5,000, stool=hem pos, AMY, Scr & BS=normal, UA= neg; 4/11/89: UGI w/KUB=WNL; Abd US=hepatic parenchyma is dense c/w fatty infiltration or hepatocellular disease				G. All manufacturers			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) H/O unspecified liver problems & gall stones; consumer denies ETOH use; consultation note from hosp (4/10/89) indicate pt has been drinking a couple of ETOH beverages/day & was told liver was bad about 6 months ago; but continues to drink; PMH (4/10/89) is significant for a tummy tuck, hysterectomy & mild HTN; 10/5/98: admitted for (See Sec C10)				1. Contact office - name/address (& mfring site for devices) McNeil Consumer Products Company Medical Affairs 7050 [redacted] Road Ft. Washington, PA 19034 DSS FFB 24 1999		2. Phone number 215-273-7820	
				4. Date received by manufacturer (mo/day/yr) 02/12/99		3. Report source (check all that apply) () foreign () study () literature (X) consumer () health professional () user facility () company representative () distributor () other:	
				6. If IND, protocol #		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 # 2		8. Adverse event term(s) HEPATOMEGALY PAIN ABDOMINAL NAUSEA HEPATITIS LIVER FATTY	
				9. Mfr. report number 0878632A			
				E. Initial reporter			
				1. Name, address & phone # [redacted] MD Suite [redacted] [redacted] Street [redacted]		BY: [redacted]	
2. Health professional? (X) Yes () No		3. Occupation physician		4. Initial reporter also sent report to FDA () Yes () No (X) Yes			