



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

Approved by FDA on 11/15/03

Mfr report # _____
 UP/Date report # _____
 FDA use only

Page ____ of ____

A. Patient information				C. Suspect medication(s)			
1. Patient identifier In confidence	2. Age at time of event: or 66 yrs Date of birth:	3. Sex (X) female () male	4. Weight 149 lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 Regular Strength TYLENOL Tablets #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 6/9/99-6/29/99; 21 days #2	
B. Adverse event or product problem				2. Dose, frequency & route used #1 650 mg, 7x daily, po #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 fever #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 () hospitalization - initial or prolonged () disability () congenital anomaly () required intervention to prevent permanent impairment/damage (X) other: none				8. Lot # (if known) #1 P1975 #2		7. Exp. date (if known) #1 11/30/01 #2	
3. Date of event (mo/day/yr) 6/9/99		4. Date of this report (mo/day/yr) 06/30/99		9. NDC # - for product problems only (if known)			
5. Describe event or problem Consumer report of ACCIDENTAL OVERDOSE and LIVER FUNCTION TESTS ABNORMAL (liver enzymes up) allegedly associated with Regular Strength TYLENOL acetaminophen Tablets. According to consumer, she has been taking 14 tablets daily (4550 mg) for the last 2 weeks per her doctor's instructions to treat fever. Recent blood work showed an unspecified increase in her liver enzymes.				10. Concomitant medical products and therapy dates (exclude treatment of event) none			
6. Relevant tests/laboratory data, including dates unspecified blood tests= liver enzymes up				G. All manufacturers			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) no known conditions; allergic to CIPRO				1. Contact office - name/address (& mfrng 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 manufacture (mo/day/yr) 06/30/99		3. Report source (check all that apply) () foreign () study () literature (X) consumer () health professional () user facility () company representative () distributor () other:	
				6. If IND, protocol #		(A) NDA # 19-872 IND # PLA # pre-1938 () Yes	
				7. Type of report (check all that apply) () 5-day () 15-day () 10-day (X) periodic (X) initial () follow-up #		OTC product (X) Yes	
				9. Mfr. report number 1200783A		8. Adverse event term(s) OVERDOSE ACCID LIVER FUNC ABNO	
				E. Initial reporter			
				1. Name, address & phone #			
				AUG - 9 2000			
2. Health professional? () Yes () No		3. Occupation		4. Initial reporter also sent report to FDA () Yes () No () 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.

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