



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

Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

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A. Patient information				C. Suspect medication(s)			
1. Patient identifier In confidence	2. Age at time of event: adult or Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 <b>TYLENOL Analgesic Unknown</b> #2			
B. Adverse event or product problem				2. Dose, frequency & route used #1 unknown dose #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates #2	
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnosis for use (indication) #1 unknown #2		5. Event abated after use stopped or dose reduced #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				6. Lot # (if known) #1 unknown #2		7. Exp. date (if known) #1 unknown #2	
3. Date of event (mo/day/yr) unknown		4. Date of this report (mo/day/yr) 10/12/99		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
5. Describe event or problem Consumer alleges that the use of one of our <b>TYLENOL®</b> acetaminophen products was associated with <b>BILIRUBINEMIA</b> (bilirubin is high). No further information was provided.				9. NDC # - for product problems only (if known)			
6. Relevant tests/laboratory data, including dates bilirubin at an undetermined time last year: 510, bilirubin at an undetermined time: 562				10. Concomitant medical products and therapy dates (exclude treatment of event) <b>COLUMADIN®, LANOXIN®</b>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) open heart surgery, 1974; allergies unknown				G. All manufacturers			
				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) 10/11/99		3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature (X) consumer  ( ) health professional ( ) user facility ( ) company representative ( ) distributor ( ) other:	
				6. If IND, protocol #		5. (A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	
				7. Type of report (check all that apply) ( ) 5-day ( ) 15-day ( ) 10-day (X) periodic (X) initial ( ) follow-up #		8. Adverse event term(s) <b>BILIRUBINEMIA</b>	
				9. Mfr. report number 1250436A			
				E. Initial reporter			
				1. Name, address & phone #			
				2. Health professional? ( ) Yes ( ) No		3. Occupation	
						4. Initial reporter sent report to FDA AUG - 9 2000 ( ) Yes ( ) No ( ) Unc	



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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