



A. Patient information				C. Suspect medication(s)					
1. Patient identifier [redacted] In confidence	2. Age at time of event: or Date of birth: 11/15/1930	3. Sex (X) female () male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unknown TYLENOL product #2 unknown TYLENOL® PM product (See Sect C10)					
2. Dose, frequency & route used #1 1000 mg, bid-tid, po #2 1, qhs, po				3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates; "routinely" #2 unknown dates; "routinely"					
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:				4. Diagnosis for use (indication) #1 unknown #2 unknown		5. Event abated after use stopped or dose reduced #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A			
3. Date of event (mo/day/yr) 2/14/00		4. Date of this report (mo/day/yr) 04/07/00		6. Lot # (if known) #1 Unknown #2 unknown		7. Exp. date (if known) #1 Unknown #2 unknown			
5. Describe event or problem Rph report rec'd via affiliate (Mfr Rpt No PRIUSA2000001665) of acute HEPATITIS allegedly associated w/ use of an unk TYLENOL® APAP product, unk TYLENOL® PM product, or LEVAQUIN® in a 70 yo F. Note from Rph indicates pt "had been using TYLENOL® routinely at home (1000 mg 2-3x/day + TYLENOL® PM at bedtime)." Hosp ADE Reporting Form indicates, on 2/14/00, pt dx'd w/acute hepatitis. Suspected drugs listed as "acetaminophen (vs. viral-induced) or levofloxacin." Other sx's included: MALAISE, DYSPNEA, TACHYCARDIA, incr LFT's (LFT's ABNORMAL), incr bili(BILIRUBINEMIA), & incr INR(PT INCREASE). Form indicates APAP cont'd q12 hrs prn. Actions taken indicates pt "put on vanco/imipenem/cipro to cover pneumonitis, serum toxicity screen, lactulose, vitamin K." Note from Rph states "gastroenterologist later felt that increase in LFT's were more likely caused by hepatic congestion secondary to severe heart failure." Addl info rec'd 4/5/00: Note from Rph rec'd via affiliate states pt's LFT's improved during hosp stay 2/15/00 thru 2/23/00. Per MD note: rapid decline(See Sect B7)				9. NDC # - for product problems only (if known) - -				8. Event reappeared after reintroduction #1 () Yes () No (X) N/A #2 () Yes () No (X) N/A	
6. Relevant tests/laboratory data, including dates 2/14/00: NH3=102, lactic acid=7.2; 2/15/00: BUN=36, AST=15046, ALT=9072, INR=3.48; 2/16/00: TBili=2.8, alk phos=131, AST=4946, ALT=5681; 2/17/00: AST=1136, ALT=2868; 2/18/00: AST=673, ALT=2275; 2/19/00: AST=257, ALT=1502; 2/20/00: AST=130, (See Sect B7) APR 14 2000				10. Concomitant medical products and therapy dates (exclude treatment of event) SYNTHROID®, ZOLOFT®, loratadine, lorazepam, vit E & C, calcium, famotidine (Sect C1 Cont): #3 LEVAQUIN®, unk dose, po, 2/11/00-unk, for pneumonia (organism unspecified)(Sect B6 Cont): AST=96, ALT=858; 2/22/00: AST=69, ALT=564; 2/23/00: AST=72, ALT=435				G. All manufacturers	
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) severe heart failure; allergic to PCN & codeine (Sect B5 Cont): in AST from 15,046 to 673 in 3 days most c/w acute Rt congestion (severe CHF). APAP 650mg po/PR q12h prn d/c'd on 2/16/00. MAR did not indicate any doses were given. Chart did not contain info on how pt is presently doing." Pt d/c'd on 2/23/00. (Sect B6 Cont): ALT=947; 2/21/00: (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) 04/05/00		3. Report source (check all that apply) () foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:			
				5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes		RECEIVED APR 13 2000 CLIN EVALUATION AND RESEARCH			
				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) HEPATITIS MALAISE DYSPNEA TACHYCARDIA LIVER FUNC ABNO BILIRUBINEMIA PROTHROMBIN INC			
				9. Mfr. report number 1340660A					
				E. Initial reporter					
				1. Name, address & phone # [redacted]					
2. Health professional? (X) Yes () No		3. Occupation pharmacist		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