



Approved by FDA on 11/15/93

Mfr report #
UF/Dist report #
FDA use only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM VALUATION AND RESERVE Page \_\_\_ of \_\_\_

<b>A. Patient information</b>				<b>C. Suspect medication(s)</b>			
1. Patient identifier Case 2 In confidence	2. Age at time of event: 38 yrs Date of birth:	3. Sex ( ) female (X) male	4. Weight unk lbs or kgs	1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified acetaminophen product #2		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown dates or duration #2	
<b>B. Adverse event or product problem</b>				2. Dose, frequency & route used #1 unknown dose, po #2			
1. X Adverse event and/or Product problem (e.g., defects/malfunctions)				4. Diagnose 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 (X) hospitalization - initial or prolonged ( ) disability ( ) congenital anomaly ( ) required intervention to prevent permanent impairment/disfigurement ( ) other:				6. Lot # (if known) #1 unknown #2		7. Exp. date (if known) #1 unknown #2	
3. Date of event - unknown (mo/day/yr)		4. Date of this report 11/02/99 (mo/day/yr)		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A			
5. Describe event or problem Case abstract #53 from the 1999 NACCT Annual Meeting (J Toxicol Clin Toxicol 1999;37(5):604) of false (+) ethylene glycol (EG) determination by enzyme assay in pts w/chronic APAP hepatotoxicity. According to abstract, serum EG determinations are usually performed by glycerol dehydrogenase (GDH) enzyme assay or gas chromatography. A recent report suggests that false (+) results by enzymatic assay may occur in the presence of elevated LDH and/or lactate resulting in increased production of NADH, the product of GDH enzymatic rxn. Authors of abstract report on 3 pts identified as having fulminant hepatic failure (LIVER FAILURE), hx of chronic APAP abuse & high anion gap metabolic ACIDOSIS. Each pt had EG levels by GDH enzyme assay greater than or equal to 20mg/dL. Case 2 had an AST=12,464 IU/L (SGOT INCREASED) & LDH=39,907 IU/L (LDH INCREASED). Tx was initiated with fomepizole. In all 3 cases the elevated EG by GDH enzyme assay was later determined to be (-) by gas chromatography. Authors conclude the false (+) results were most likely(See Sect 87)				9. NDC # - for product problems only (if known)			
6. Relevant tests/laboratory data, including dates Unspecified time:anion gap=45, AST=12,464 IU/L,LDH=39,907 IU/L,lactate=14.6 mmol/L; new info rec'd 10/28/99: Upon presentation:pH=7.15,AST=8580IU/L,Tbili=2.5mg/dL, ammonia=119umol/L,INR=6.1,Cr=1.8mg/dL,APAP level=31mcg/ml,EG=50mg/dL				10. Concomitant medical products and therapy dates (exclude treatment of event) unknown (Sect 87 cont) pt unresponsive & pH=7.15, AST=8580 Tbili=2.5 (BILIRUBINEMIA), NH3=119 (NPN INCREASED), INR=6.1 (PROTHROMBIN INCREASED), creatinine=1.8 (CREATININE INCREASED) & APAP=31. Pt tx w/NAC & one dose of IV fomepizole.			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) history of chronic APAP & ETOH abuse; (Sect 85 cont) due to increases in LDH &/or lactate assoc w/liver failure & acidosis.Addl info rec'd 10/28/99:Case abstract#180 from1999NACCT Annual Meeting (JToxClinTox 1999;37(5):656-7) describes the same pt, as verified by author. Pt is a 38 yo male w/hx of chronic ETOH & APAP abuse. On presentation, (See Sect10)				<b>G. All manufacturers</b>			
				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) 10/28/99		3. Report source (check all that apply) ( ) foreign ( ) study (X) literature ( ) consumer  health professional (X) professional ( ) user facility  comp: 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 (X) 15-day ( ) 10-day ( ) periodic ( ) Initial (X) follow-up # 1		8. Adverse event term(s) LIVER FAILURE ACIDOSIS SGOT INCREASED LDH INC BILIRUBINEMIA NPN INCREASED PROTHROMBIN INC CREATININE INC	
				9. Mfr. report number 1254566A			
				<b>E. Initial reporter</b>			
				1. Name, address & phone # [REDACTED] MD [REDACTED] [REDACTED]		NOV 8 1993	
				2. Health professional? (X) Yes ( ) No		3. Occupation physician	
				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 contributed to the event.