



facilities,
manufacturers for
reporting.

APPROVED BY FDA ON 03/06/98

Mfr report #	203796
UF/Dist. report #	
FDA Use only	

THE MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information			
1. Patient identifier	2. Age at time of event: or _____ UNK Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight _____ UNK lbs or _____ kgs
In confidence			
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply)			
<input type="checkbox"/> death / / (mortality)		<input type="checkbox"/> disability	
<input type="checkbox"/> life threatening		<input type="checkbox"/> congenital anomaly	
<input type="checkbox"/> hospitalization initial or prolonge		<input type="checkbox"/> permanent impairment/damage	
		<input checked="" type="checkbox"/> other: NON-SERIOUS	
3. Date of event UNK / / (month/year)		4. Date of this report DEC / 14 / 1999 (month/year)	
5. Describe event or problem			
<p>A FEMALE CONSUMER OF UNSPECIFIED AGE HAD AN ABNORMAL LIVER FUNCTION TEST DURING THE USE OF VALIUM TABLETS (DIAZEPAM), EXTRA STRENGTH TYLENOL PM (DIPHENHYDRAMINE HCL/PARACETAMOL) AND UNISOM (DOXYLAMINE) FOR SLEEP DISORDER.</p> <p>MEDICAL HISTORY: THE CONSUMER'S HUSBAND DIED A FEW YEARS PREVIOUSLY AND AS A RESULT SHE WAS HAVING TROUBLE SLEEPING AT NIGHT. SHE HAD NO PRIOR HISTORY OF LIVER DISEASE AND NO KNOWN DRUG ALLERGIES. SHE DENIED ETOH (ETHANOL) USE. 1996 (EST.): VALIUM 5 MG TABLET HS, UNISOM 1 TABLET HS AND EXTRA STRENGTH TYLENOL PM GELTABS X 2 HS WERE STARTED WITH THE CONSUMER'S PHYSICIAN'S KNOWLEDGE.</p> <p>DATE UNKNOWN: A BLOOD ANALYSIS SHOWED AN ABNORMAL LIVER FUNCTION TEST OF 55 (THE LIVER FUNCTION TEST WAS NOT SPECIFIED AND THE LAB VALUES AND NORMAL RANGES WERE NOT PROVIDED). THE CONSUMER'S MEDICATIONS WERE CONTINUED. 15 MAR 99: AT THE TIME OF THE REPORT THE OUTCOME OF THE ABNORMAL LIVER FUNCTION TEST WAS NOT PROVIDED.</p>			
6. Relevant tests/laboratory data, including dates			
<p>LIVER FUNCTION TEST LAB RESULT: 55 (UNSPECIFIED LIVER TEST).</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)			
<p>Medical History Text THE CONSUMER'S HUSBAND DIED A FEW YEARS PREVIOUSLY AND AS A RESULT SHE WAS HAVING TROUBLE SLEEPING AT NIGHT. SHE NO PRIOR HISTORY OF LIVER DISEASE AND NO KNOWN DRUG ALLERGIES. SHE DENIED ETOH (ETHANOL) USE.</p>			

C. Suspect medication(s)	
1. Name (give labeled strength & manufacturer, if known)	
#1 VALIUM TABLETS (DIAZEPAM) 5 MG	
#2 UNISOM (DOXYLAMINE SUCCINATE)	
2. Dose, frequency & route	
#1 5 MG 1 per DAY ORAL	
#2 1 DOSE FORM 1 per DAY ORAL	
3. Therapy dates (if unk. give duration from/to (or best estimate))	
#1 15-JUN-1998 E / CONTINUING	
#2 15-JUN-1996 E / CONTINUING	
4. Diagnosis for use (indication)	
#1 SLEEP DISORDER	
#2 SLEEP DISORDER	
5. Event abated after use stopped or dose reduced	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
6. Lot # (if known)	
#1 UNK	
#2 UNK	
7. Exp. date (if known)	
#1 UNK	
#2 UNK	
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # for product problems only (if known)	
#1 NA #2 NA	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
UNK	
DEC 1 5 1999	

G. All manufacturers	
1. Contact Office-name/address	
GLOBAL DEVELOPMENT HOFFMANN-LA ROCHE INC. 340 KINGSLAND STREET NUTLEY, NJ 07110-1199	
2. Phone Number	
(973) 582-3523	
3. Report source (check all that apply)	
<input type="checkbox"/> foreign	
<input type="checkbox"/> study	
<input type="checkbox"/> literature	
<input type="checkbox"/> consumer	
<input checked="" type="checkbox"/> health professional	
<input type="checkbox"/> user-facility	
<input type="checkbox"/> company representative	
<input type="checkbox"/> distributor	
<input type="checkbox"/> other:	
4. Date received by manufacturer	
APR / 6 / 1999	
5. (A)NDA# 13-263	
IND # _____	
PLA # _____	
pre-1938 <input type="checkbox"/> yes	
OTC <input type="checkbox"/> yes	
product <input type="checkbox"/> yes	
6. If IND, protocol #	
NA	
7. Type of report (check all that apply)	
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic	
<input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	
8. Adverse event term(s)	
ABNORMAL LIVER FUNCTION TEST +++	
9. MFR report number	
203796	
+++ adverse event that generated submission	

E. Initial reporter			
1. Name, address & phone #			
ERICA C KOBYLINSKI MCNEIL CONSUMER HEALTHCARE 7050 CAMP HILL ROAD FORT WASHINGTON PENNSYLVANIA 19034-2299 UNITED STATES OF AMERICA			
2. Health professional?			
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no			
3. Occupation			
PHARMACIST			
4. Initial reporter also sent report to FDA			
<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk.			

CONTINUED



Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

E-Indicates estimated date, P-Indicates partial date



Mfr report # 203796

C.1. thru C.9. Suspect medication(s) - continued

Suspect medication #3

C.1. Name and Strength (give mfr/labeler, if known)
EXTRA STRENGTH TYLENOL PM (ACETAMINOPHEN/DIPHENHYDRAMINE HYDROCHLORIDE)

C.2. Dose, frequency and route
2 DOSE FORM 1 per DAY ORAL

C.3. Therapy dates (if unk. give duration) from/to or best estimate
15-JUN-1996 E / CONTINUING

C.4. Diagnosis for use (indication)
SLEEP DISORDER

C.5. Event abated after use stopped or dose reduced
DOESNT APPLY

C.6. Lot # (if known)
UNK

C.7. Exp. date
UNK

C.8. Event reappeared after reintroduction
DOESNT APPLY

C.9. NDC # - for product problems only
NA

DEC 15 1999

E.1. Initial reporter (Name, address & phone #) - continued

PHONE: 215-273-7328