

Lemley, Lee

From: Natalie Hartenbaum [NataH@worldnet.att.net]
Sent: Monday, October 15, 2001 4:18 PM
To: Lemley, Lee
Subject: Re: Witness List

4816 OCT 19 10:19



natbio100.doc



sedation - meds.doc



frameds.pdf



med question.doc

I have attached my bio and some

possible material to be included. I suspect

that many of the regulatory documents will come from the government witnesses. I have included a sample questionnaire which may be used by some companies or medical examiners.

There is also a pamphlet from the FAA entitled Over the Counter Medications

and Flying. If Dr. Parmet does not submit that, please let me know and I

will attempt to find an additional copy. Many of the companies I

----- Original Message -----

From: "Lemley, Lee" <LemleyL@cderr.fda.gov>

To: <natah@att.net>

Sent: Friday, October 12, 2001 3:47 PM

Subject: Witness List

> Dr. Hartenbaum,

>

> I am sorry I missed your call. I have attached the current witness list.

>

> If you have any further questions, please give me a call on Monday.

>

> Thank you

>

>

> <<Witnesses101201.rtf>>

>

> Lee Lemley

> Policy Analyst

> CDER Executive Operations Staff

> (301) 594-6218 - lemleyl@cderr.fda.gov

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>

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OIN-0397

C 1

Medication Effects on Driving

Selected References

Prepared by

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President and Chief Medical Officer
OccuMedix, Inc Dresher, PA

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directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program)

Issued on: December 15, 1998.

Elton H. Chang,

Environmental Engineer Oregon Division.

[FR Doc. 98-34177 Filed 12-23-98; 8:45 am]

BILLING CODE 4910-01-M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Safe Use of Prescription and Over-the-Counter Drugs

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of safety advisory.

SUMMARY: FRA issues Safety Advisory 98-3 to address recommended practices for the safe use of prescription and over-the-counter drugs by safety-sensitive railroad employees.

FOR FURTHER INFORMATION CONTACT:

Lamar Allen, Alcohol and Drug Program Manager, Office of Safety Assurance and Compliance, Operating Practices Division, Federal Railroad Administration, 1120 Vermont Avenue, NW, RRS-11, Mail Stop 25, Washington, DC 20590. (Telephone: (202) 493-6313) or Patricia V. Sun, Trial Attorney, Office of Chief Counsel, FRA, 1120 Vermont Avenue, NW, RCC-11, Mail Stop 10, Washington, DC 20590. (Telephone: (202) 493-6060).

SUPPLEMENTARY INFORMATION: FRA issues this advisory in support of DOT's efforts to ensure that transportation employees safely use prescription and over-the-counter (OTC) drugs. Safe rail operations depend upon alert and fully functional professionals who have not been adversely affected by drug use, whether medically appropriate ("legal") or not. FRA has always prohibited illicit drug use and unauthorized use of controlled substances by safety-sensitive employees, but is equally concerned about the potentially adverse side effects from other prescription drugs and OTC products. Because DOT and FRA testing (including FRA's post-accident program) targets only alcohol and controlled substances, FRA does not have a clear picture of the extent to which the performance of safety-sensitive employees is adversely affected by legal drug use.

Accordingly, although not specifically addressed in its alcohol and drug testing regulations (49 CFR part 219), FRA strongly recommends that rail employers and safety-sensitive employees follow § 219.103 guidelines when considering the use of all prescription and OTC drugs. Simply stated, in the interest of safety, FRA strongly recommends that either a treating medical professional or a railroad-designated physician make a fitness-for-work determination concerning all prescription and OTC drug use prior to permitting an employee to return to work in safety sensitive service. This determination should also be made whenever an employee currently performing safety-sensitive functions is concerned about possible effects on his or her job performance from the use of prescription or OTC drugs.

Section 219.103(b) authorizes railroads to establish reporting and approval procedures for all prescription and OTC drugs which may have detrimental effects on safety. Additionally, FRA recommends that railroads educate their employees on these reporting and approval procedures and, most importantly, on how to use prescription and OTC medications safely.

FRA will take all appropriate action to continue reducing the negative impact from inappropriate use of all prescription and OTC medications. Moreover, FRA strongly encourages the rail industry to voluntarily develop programs on safe prescription and OTC drug use before such programs are mandated or directed through legislation.

Issued in Washington, D.C., on December 16, 1998.

George Gavalla,

Acting Associate Administrator for Safety.

[FR Doc. 98-34054 Filed 12-23-98; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration (RSPA), DOT

[Docket No. RSPA-98-4450; Notice 17]

Pipeline Safety: Intent To Approve Project and Environmental Assessment for the Chevron Pipe Line Company; Pipeline Risk Management Demonstration Program

AGENCY: Research and Special Programs Administration, Office of Pipeline Safety, DOT.

ACTION: Notice of Intent to Approve Project and Environmental Assessment.

SUMMARY: As part of its Congressional mandate to conduct a Risk Management Demonstration Program, the Office of Pipeline Safety (OPS) has been authorized to conduct demonstration projects with pipeline operators to determine how risk management might be used to complement and improve the existing Federal pipeline safety regulatory process. This is a notice that OPS intends to approve Chevron Pipe Line Company (Chevron) as a participant in the Pipeline Risk Management Demonstration Program. This also provides an environmental assessment of Chevron's demonstration project. Based on this environmental assessment, OPS has preliminarily concluded that this proposed project will not have significant environmental impacts.

This notice explains OPS's rationale for approving this project, and summarizes the demonstration project provisions that would go into effect once OPS issues an order approving Chevron as a Demonstration Program participant. OPS seeks public comment on the proposed demonstration project so it may consider and address these comments before approving the project. The Chevron demonstration project is one of several projects OPS plans to approve and monitor in assessing risk management as a component of the Federal pipeline safety regulatory program.

ADDRESSES: OPS requests that comments to this notice or about this environmental assessment be submitted on or before February 8, 1999, so they can be considered before project approval. However, comments on this or any other demonstration project will be accepted in the Docket throughout the 4-year demonstration period. Comments should be sent to the Dockets Facility, U.S. Department of Transportation, Plaza 401, 400 Seventh Street, SW, Washington, DC 20590-0001, or you can E-Mail your comments to ops.comments@rspa.dot.gov. Comments should identify the docket number RSPA-98-4450. Persons should submit the original comment document and one (1) copy. Persons wishing to receive confirmation of receipt of their comments must include a self-addressed stamped postcard. The Dockets Facility is located on the plaza level of the Nassif Building in Room 401, 400 Seventh Street, SW, Washington, DC. The Dockets Facility is open from 9:00 a.m. to 5:00 p.m., Monday through Friday, except on Federal holidays.

OccuMedix, Inc

MEDICATION QUESTIONNAIRE

Re: _____ S.S. Number _____
Date: _____

Dear Doctor:

The above patient/driver is being evaluated to determine whether he/she meets the medical standards of the Federal Motor Carrier Safety Administration (FMCSA) to operate a commercial motor vehicle. The FMCSA explains that a commercial driver "must have the perceptual skills to monitor a sometimes complex driving situation," and "the judgment skills to make quick decisions." There is increasing recognition that both prescription and non-prescription medications can impair the performance of tasks requiring concentration, such as driving.

Please provide the following information:

1. How long have you been treating this patient? _____
2. Please list medications, dosage, and duration of treatment at the current dose. _____

3. Have there been any side effects such as sedation or decreased concentration? Yes No
4. If so, please explain _____

5. Is he/she using any of these medications to treat a condition that is likely to interfere with the safe operation of a commercial motor vehicle? Yes No
6. If so, please explain: _____

7. Considering the complex mental requirements of operating a commercial motor vehicle, and after reviewing the attached Federal guidelines, do you believe your patient can safely operate such a vehicle while taking the above medications? Yes No

Physician Name _____ Signature _____

Phone # _____ Date _____