



January 31, 2000

**Mr. Jim Hall, Chairman
Executive Secretariat Division (MD-5)
National Transportation Safety Board
Washington, D.C. 20594**

Dear Chairman Hall:

I am writing to you regarding your recommendations for the labeling of prescription and over-the-counter medications. In particular, you recommended that we establish a clear, consistent, easily recognizable warning label for all prescription and over-the-counter (OTC) medications that may interfere with an individual's ability to operate a vehicle and that we require that the label be prominently displayed on all packaging of such medications.

I agree that we need to provide consumers with clearly understandable labels on how to properly use medications so they can obtain the benefits provided by today's medicines while minimizing possible risks. This is a critical part of FDA's mission as a public health service agency.

In the case of OTC or nonprescription drugs, the information that consumers need is provided on the drug product's packaging. FDA regulates the information provided on this packaging to ensure that appropriate instructions for use, warnings, and other important information is provided.

The packaging of certain drugs that may affect the ability to drive must include appropriate precautionary statements. FDA already requires a warning for all OTC drug products (e.g., antihistamines, antitussives, antiemetics, and nighttime sleep-aids) that may interfere with an individual's ability to operate a vehicle. That warning states: "Use caution when driving a motor vehicle or operating machinery."

While this statement must appear under the warnings part of the labeling, until recently there was no requirement that it appear in a specific place. On March 17, 1999 (64 FR 13254), FDA published a new regulation, "Labeling Requirements for Over-The-Counter Human Drugs," that will further standardize the content and format for labeling OTC drug products and make it easier for consumers to appropriately select and use these products.

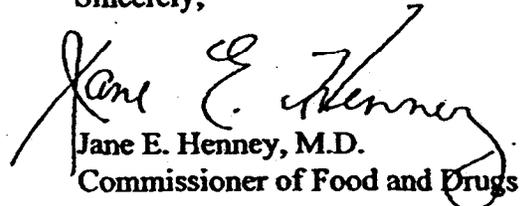
Under FDA's new regulation, the warning statement will be prominently displayed under the subheading "When using this product," and will read "be careful when driving a motor vehicle or operating machinery." The new labeling requirements include a 6-point minimum type size to

make the labeling more legible and readable, along with the warning information being in a consistent location in the product's labeling. I think the new format of the warnings will meet NTSB's criteria of being clear, consistent, and easily recognizable by consumers.

The labeling for prescription drugs is developed by many different organizations. Individual state boards of pharmacy regulate the labels that accompany the prescription drug products that are dispensed to consumers. FDA approves the package insert labeling and labels of the prescription drug products that are on the shelves of pharmacies. Currently, FDA requires that appropriate instructions for use, warnings, and other important information appear in the package insert labeling directed to health care practitioners. For sedating drugs, there is almost always a clear warning about use in patients who drive or operate heavy machinery. In addition, privately developed patient labeling or patient information may be included when there is important risk information that must be communicated and usually includes such warnings. As you may know, FDA is to evaluate the adequacy of private patient information in 2001. Certainly, the adequacy of the significant warning information, such as effects on driving, will be considered.

Thank you for your recommendations. FDA is interested in all proposals and ideas intended to enhance consumers' ability to use medicines effectively and safely. We will give careful consideration to the information and ideas provided in the NTSB analysis.

Sincerely,



Jane E. Henney, M.D.
Commissioner of Food and Drugs