HERCULES®

Hercules Chemical Company Inc.
111 South Street
Passaic, New Jersey
07055-9100

Tel. 973.778.5000
Fax. 973.778.5823
www.herchem.com

February 22, 2001

Dockets Management Branch (HFA 1-305)
Docket Number: PPN-1269
Food and Drug Administration
5530 Fishers Lane, Room 1061
Rockville, MD 20857

1

RE: DRUG LABEL NEWS ARTICLE BY LINDA MARSA, LOS ANGELES TIMES

Gentlemen/Ladies:

This letter is being sent by the Chairman of the Board of the company designated on this letterhead. Having had the good fortune to lead this business through most of the years since 1946, I have had substantial direct experience with packaging, labeling, and innumerable regulations on international, national, regional and local levels. While this experience does not relate directly to food or drugs, it has always had direct correlation to providing our users with packages containing clear, readable, legible descriptions and instructions for proper use of the products contained in each package (some including hazardous ingredients).

In recent years (I shall be 80 in 2002), physicians have prevailed on me to start taking prescriptions to treat glaucoma, a moderate heart affliction and some other physical imperfections.

My daily prescription use currently amounts to eight different medications used daily once, twice, or three times.

For some years I have been perplexed by the ridiculously small print on almost every package, bottle, or label accompanying each medication. The biggest joke of all is the multi-fold insert which almost always accompanies eye-drop medications which are packaged in a dropper-style bottle inside a paper-board container.

- Continued -

00N-1269 C9

HERCULES® Cloroben®

Hercules Chemical Company Inc. manufactures and markets Hercules and Cloroben fine products.

How ironic that 2 point or 4 point type is "fed" to glaucoma sufferers who can't even read albeit understand the vital information contained in these leaflets, even with visual correction equipment.

This raises another problem which cries out for an answer. Somehow, medical terminology which can usually be understood only by trained persons sits cheek by jowl with information intended for the average consumer. Self-defeating, to say the least.

It is my sincere hope that smart people working on this problem at FDA will find reasonable answers soon. Of course, nothing beats cures for the basic illnesses. But some interim assistance can benefit many greatly.

Yours sincerely,

HERCULES CHEMICAL COMPANY, INC.

Jay W. Fidler
Chairman

JWF:mee

Reading drug labels is about to get easier

New FDA format designed to aid consumers, doctors

Linda Marsa
Los Angeles Times

Trying to decipher the medical jargon on drug labels can be daunting for the average consumer. Even doctors have trouble. But the stakes are high: Research suggests that medication errors may be responsible for as many as 100,000 U.S. deaths each year.

The Food and Drug Administration hopes to stem this mounting toll by making drug labels — the package inserts that come with medications — more user friendly. Doctors can then get the crucial information they need at a glance, rather than having to wade through reams of complex medical data.

The new format makes it easier for consumers to read the package inserts, too, so they can be more aware — and thus more vigilant — about possible problems.

"We hope the new labeling will reduce medical errors, which are an important cause of hospitalizations, serious injury and drug interactions," says Nancy Ostrove, chief of research for the FDA's Center for Drug Evaluation and Research. "The proposed changes would make pertinent information clear, concise, comprehensive and easily accessible."

Drug package inserts contain many caveats about potential problems, including possible adverse reactions or interactions with other drugs, buried in fine print that harried physicians often don't have time to read. Small wonder simple mistakes are often made that can be catastrophic for patients.

"Doctors can miss warnings about drugs, or not prescribe the right dosages," says Mike Pavlovich, a pharmacist in Torrance, Calif., and president of the California Pharmacists Association.

The FDA has long known there was a problem, as doctors have complained that the labels are too lengthy and complicated to use efficiently. The agency began surveying physicians in 1992 to determine what changes should be made. Based on these surveys, the agency overhauled product labels.

The new format now has an introductory "highlights" section containing the most crucial information. Physicians identified several categories of information they need upfront: common side effects, significant adverse reactions, drug interactions, proper dosages, how the drug's effectiveness compares to similar medications, and warnings for specific populations, such as children, pregnant women or the elderly.

Section headings are in a dark bold, enlarged typeface, and the labels are uniform in their presentation, in the same way as food labels list essential nutrition facts.

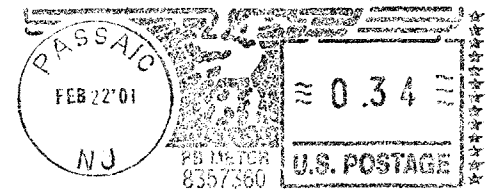
The FDA also has proposed stamping an inverted black pyramid on novel therapies that are either new formulations or have been on the U.S. market for less than three years. Experts know that unanticipated reactions occur most frequently in newly marketed drugs. This emblem, which is in use in Great Britain, will serve as a signal to doctors to use extra care, and to be on the lookout for rare but potentially serious side effects.

The FDA plans to phase in the changes. In addition, it is still soliciting comments on the changes. If you want to weigh in, the deadline is March 22.

The changes are available on www.fda.gov/ohrms/dockets/98fr/122200a.htm).

Or you can submit written comments to Dockets Management Branch (HFA-305), Docket Number: 00N-1269, Food and Drug Administration, 5530 Fishers Lane, Room 1061, Rockville, MD 20857.

HERCULES®
CHEMICAL
COMPANY
INCORPORATED
111 SOUTH STREET
PASSAIC, NJ 07055-7398



Dockets Management Branch (HFA 1-305)
Docket Number: PPN-1269
Food and Drug Administration
5530 Fishers Lane, Room 1061
Rockville, MD 20857