



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 08 2001

Food and Drug Administration
Rockville MD 20857

Leonore A. Herzenberg, Ph.D.
Department of Genetics
Stanford University
Beckman Center, B-007
Stanford, California 94305-5125

John James
AIDS Treatment News
273 Church
San Francisco, California 94114

Rec'd 8/17/01

Re: Docket No. 97P-0102/CP1

Dear Dr. Herzenberg and Mr. James:

This is an interim response to your petition dated February 14, 1997. The petition requests that the Food and Drug Administration investigate whether glutathione (GSH)-depleting drugs, acetaminophen in particular, should be labeled with a warning against excessive or unnecessary use by HIV-infected individuals.

You state that a number of studies have demonstrated a pronounced GSH deficiency in HIV-infected adults and children that increases as the disease progresses. You suggest that certain drugs, including acetaminophen, tend to deplete GSH and that those drugs are potentially more toxic to people with GSH deficiency. You also state that such drugs could be harmful to HIV-infected individuals, especially those with AIDS, if used at dosages that are within the upper safe-dosage range for uninfected individuals.

The Agency is conducting a broad evaluation of the toxicity of acetaminophen in various populations, in specific clinical situations, and at different dosages. Part of this evaluation includes a review of the possible need for revised labeling. The issues raised in your petition are being addressed in this evaluation. We will respond to your petition when this evaluation is complete, which should be in the near future.

In discussions with staff from the Division of OTC Drug Products, you indicated that you have additional data relevant to this issue. I encourage you to submit this information as an amendment to your petition. Any additional information should be submitted in three copies to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Be sure to identify the docket number above.

I hope this information is helpful.

Sincerely yours,

Janet Woodcock for JW
Janet Woodcock, M.D.

97P-0102

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 8.16.01

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 97P-01021

TO: Dockets Management Branch, HFA-305

- The attached material should be placed on public display under the above referenced Docket No.
- This material should be cross-referenced to Comment No. CPI


Charles J. Ganley, M.D.

Attachment