



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 31 2004

Lorraine M. D'Angelo
Director
HHS Supply Service Center
Perry Point, Maryland 21902

Re: Docket No. 98N-0337
Application for Exemption
Comment No. APP44

Dear Ms. D'Angelo:

This is in response to your Application for Exemption, received by the Food and Drug Administration (FDA) on July 30, 2003. You requested an exemption from 21 CFR 201.66 for OTC drug products that are repackaged at the HHS Supply Service Center (HHS SSC). Your request was filed as Comment No. APP44 under Docket No. 98N-0337 in FDA's Division of Dockets Management.

Your request described the process by which other federal facilities purchase OTC drug products repackaged by the HHS SSC and how these products are dispensed to entitled patients. We obtained clarification of this process in a telephone conversation between members of the HHS SSC and FDA staffs on March 2, 2004.

As explained in this telephone conversation, after reviewing your repackaging and distribution process, FDA staff determined that the repackaged products need to be labeled in accord with 21 CFR 201.66 to meet the requirements of Section 502(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 352(c)). That section of the statute states that a drug shall be deemed to be misbranded "If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

FDA staff explained that 21 CFR 201.66 is FDA's current requirement for the labeling of OTC drug products that are marketed under final OTC drug monographs or approved new drug applications. Accordingly, we are denying your request for an exemption from 21 CFR 201.66 for the products that HHS SSC repackages.

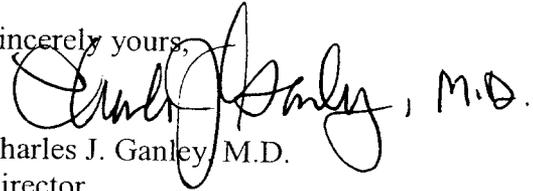
During the telephone conversation, we discussed certain products that your facility repackages and your ongoing efforts to install new equipment to revise your

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labeling for these repackaged products. We discussed a timeframe for the new labels to be implemented and asked you to update us on your progress. In addition, we discussed the need for you to examine all of your labeling to assure that all labeling requirements for OTC drug products are met, whether or not the products are covered by final OTC drug monographs.

You may provide follow-up information to Gerald M. Rachanow or Cazemiro Martin of our division. If you have any questions, please contact Mr. Rachanow or Mr. Martin at (301) 827-2222.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley, M.D.", written in a cursive style.

Charles J. Ganley, M.D.

Director

Division of OTC Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and

Research

M E M O R A N D U M

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

DATE: MAR 31 2004

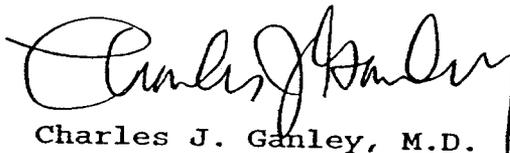
FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 98N-0337

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. APP44


Charles J. Ganley, M.D.

Attachment