DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 6 2003

Alan G. Minsk, Esquire
Arnall Golden Gregory LLP
2800 One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3450

Re: Docket No. 78N-036L
Comment No. CP27

Dear Mr. Minsk:

This is in reference to your citizen petition (CP27), dated August 30, 2002, filed under Docket No. 78N-036L in the Dockets Management Branch on September 4, 2002. The petition requests, among other things, that the Food and Drug Administration refrain from taking enforcement action after November 5, 2002, against any manufacturer of an over-the-counter (OTC) stimulant laxative drug product containing casanthranol or cascara sagrada.

You cited a final rule published in the Federal Register on May 9, 2002 (67 FR 31125), which became effective on November 5, 2002, and as of that date does not allow the initial introduction or initial delivery for introduction into interstate commerce of OTC laxative drug products that contain the aloe and cascara sagrada ingredients listed in 21 CFR 310.545(a)(12)(iv)(C). You also requested, alternatively, that FDA stay and reconsider its decision regarding these products. You made this request to allow manufacturers sufficient time to reformulate these products, which you stated have been on the market as safe and effective products for over 40 years.

The procedures governing the review of citizen petitions are set out in regulations found at 21 CFR 10.30. The regulations provide, among other things, that the Commissioner shall furnish a response to a petition within 180 days of the petition, agency resources and priorities permitting. See 21 CFR 10.30(e). As you noted in your petition, the American Herbal Products Association and the International Aloe Science Council also submitted a similar petition (Docket No. 78N-036L/CP25). Those organizations have supplemented their petition with additional information (SUP14 and SUP15) on the affected ingredients. The agency is still evaluating that information, which has a bearing on your requested actions. This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the need to complete its evaluation of the information in the other related petition (CP25) and the existence of other priorities, the agency is unable to provide a response to your petition at this time. Please note that the final rule is still in effect and we will provide a complete response to your citizen petition in the near future.

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If you have any questions regarding this matter, please refer to the docket and comment numbers noted above and submit all inquiries to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, Maryland 20852.

Sincerely yours,

FOR Janet Woodcock, M.D.
Director
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 6 2003

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

SUBJECT: Material for Docket No. 78N-036L

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. CP27

Charles J. Ganley, M.D.

Attachment