DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 6 2003

Anthony L. Young, Esquire
American Herbal Products Association
International Aloe Science Council
1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412

Re: Docket No. 78N-036L
Comments No. CP25, SUP14,
and SUP15

Dear Mr. Young:

This is in reference to your citizen petition (CP25), dated June 10, 2002, and the supplemental information that you submitted on October 28, 2002 (SUP14) and December 19, 2002 (SUP15). These documents are filed under Docket No. 78N-036L in the Dockets Management Branch. The petition requests, among other things, a stay and reconsideration of the final rule that the Food and Drug Administration (FDA) published on May 9, 2002 (67 FR 31125).

In the May 9, 2002 final rule, FDA declared the stimulant laxative ingredients aloe (including aloe extract and aloe flower extract) and cascara sagrada (including casanthranol, cascara fluidextract aromatic, cascara sagrada bark, cascara sagrada extract, and cascara sagrada fluidextract) in over-the-counter (OTC) drug products as not generally recognized as safe and effective or misbranded. The effective date of the final rule was November 5, 2002. You requested that this final rule be stayed until FDA and a relevant advisory committee have reconsidered this action based on readily available information regarding the safe and effective use of these ingredients as well as other positions, information, and requests for clarification contained in your petition.

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). This is to advise you, pursuant to 21 CFR 10.30(e)(2), that because of the additional information that you provided in October and December, which is still being reviewed, the Agency is unable to provide a response to the 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. [redacted] CP25, SUP14, SUP15

Charles J. Ganley, M.D.

Attachment