



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

1303 02 07 12 09 126

SEP 10 2002

Michael McGuffin
President
American Herbal Products Association
8484 Georgia Avenue
Suite 370
Silver Spring, Maryland 20910

Dear Mr. McGuffin:

This responds to your meeting request dated August 16, 2002 to discuss your petition to stay the effective date of the final rule for aloe and cascara sagrada as ingredients in stimulant laxative over-the-counter drug products. The primary purpose of the meeting was to discuss currently available information on cascara sagrada. You planned to bring two consultants who would discuss information available in the public domain for cascara sagrada. You also proposed to discuss descriptions of aloe vera that appeared in the Federal Register notice of May 9, 2002 and how the rulemaking impacts on the herbal supplement industry.

The Division is denying your request for a meeting at this time. The issues you want to discuss are similar to those raised in your petition. The Division is currently reviewing the information in the petition and hopes to provide a response in the near future. A meeting at this time is unlikely to further that process. If you have additional information, I suggest that you submit it to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, Room 1061, Rockville, Maryland 20852, as soon as possible. You should send the information to Docket No. 78N-036L and identify it as a Supplement to CP25.

Sincerely,

Charles J. Ganley, M.D.

Director

Division of Over-the-Counter Drug Products

Office of Drug Evaluation V

Center for Drug Evaluation and Research

78N-036L

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BY: *dyp*

August 16, 2002

Charles Ganley, M.D., Director
Gerald M. Rachanow

Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research (HFD-560)
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Re: Status of aloe and cascara sagrada in stimulant laxative drug products

Dear Dr. Ganley and Mr. Rachanow:

On June 10, 2002 the American Herbal Products Association and the International Aloe Science Council filed a petition for stay and reconsideration of the Administration's final rule regarding aloe and cascara sagrada as ingredients in stimulant laxative over-the counter drug products. This letter is to request a meeting with you and your colleagues to discuss the stay and reconsideration petitions.

Since the stay and reconsideration petitions were filed, we have engaged the Toxicology Group, LLC at NSF International to evaluate presently available cascara sagrada information in the public domain regarding the issues that the Administration requested to be addressed in its June 19, 1998 Federal Register notice. We have asked Lori Bestervelt, Ph.D. of NSF to attend the meeting and to discuss that information with you. We will provide the information to you in advance of the meeting, once it is scheduled.

Attending the meeting for the American Herbal Products Association would be me, Stephen Dentali, Ph.D., our Vice-President of Scientific & Technical Affairs, Anthony L. Young, our General Counsel, and Dr. Bestervelt. The matters we would like to discuss with you at the meeting are as follows:

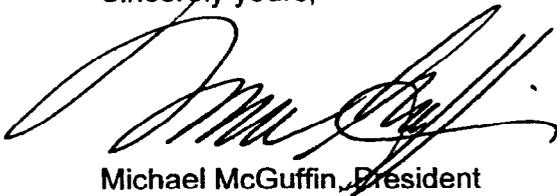
- A. The presently available information regarding cascara sagrada.

- B. The descriptions of aloe vera that appear in the Federal Register notice of May 9, 2002 and why these descriptions should be modified.
- C. The impact of the Administration's Federal Register notice on the herbal supplement industry.

We expect our requested meeting would take no more than two hours.

Please contact me so that we can find a mutually convenient time to set up this meeting. Thank you very much for your consideration of this request.

Sincerely yours,



Michael McGuffin, President

cc: Anthony Young
Lori Bestervelt

MEMORANDUM

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

DATE: SEP 10 2002

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

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

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. CP25


Charles J. Ganley, M.D.

Attachment