



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305  
Public Health Service

Rockville MD 20857

December 11, 2000

3129 '01 JAN -8 10:44

Gary Yingling  
Law Offices of McKenna & Cuneo  
1900 K Street, N.W.  
Washington, D.C. 20006-1108

Re: Docket No. 80N-0146  
Comment No. CP3

Dear Mr. Yingling:

This letter concerns your above referenced citizen petition dated February 10, 1995, filed on behalf of the Oakhurst Company. The petitioner requests that the agency establish a monograph for over-the-counter (OTC) drug products for nailbiting and thumbsucking deterrent drugs to recognize cayenne pepper as a safe and effective ingredient for use in aversive taste therapy products to deter nailbiting and thumbsucking.

For the reasons given below, the agency considers action on the petition as completed.

On May 16, 2000, Charles J. Ganley, M.D., Director, Division of OTC Drug Products, issued a letter to you (copy enclosed) concluding that the data submitted with the petition were inadequate to support your petition request.

Accordingly, this petition is denied.

If you have any questions regarding the petition, please refer to the docket and comment numbers above, and submit all inquiries, in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

Dennis E. Baker  
Associate Commissioner  
for Regulatory Affairs

Enclosure

80N-0146

PDN 3

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

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DATE:

12.30.00

FROM:

Director

Division of OTC Drug Products, HFD-560

SUBJECT:

Material for Docket No. 80N-0146

TO:

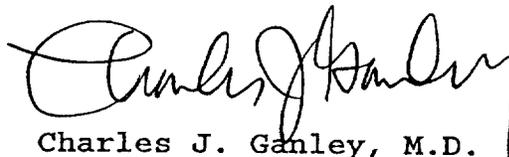
Dockets Management Branch, HFA-305



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



This material should be cross-referenced to Comment No. CP3

  
Charles J. Ganley, M.D.

Attachment