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January 10, 2001

Gary L. Yingling
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 80N-0146, Comment No. CP3
Oakhurst Company

Dear Sir or Madam:

McKenna & Cuneo, L.L.P. represents the Oakhurst Company ("Oakhurst"), a very small over-the-counter ("OTC") drug distributor, with respect to Oakhurst's petition requesting the Food and Drug Administration ("FDA") to establish an OTC drug monograph for the use of cayenne pepper as a nailbiting and/or thumbsucking deterrent product. On May 16, 2000, we received a letter from Dr. Charles J. Ganley, Director of the Division of OTC Drugs, notifying us that Oakhurst's petition, which was submitted on February 10, 1995, was inadequate and that the OTC Division was recommending that the petition be denied. Dr. Ganley's letter stated that Oakhurst could provide additional information and/or comments to this docket. Our client accepted that offer and has been diligently preparing a response since receiving Dr. Ganley's letter.

Oakhurt's efforts to respond to the agency have been delayed by the need to identify and retain scientific experts and the time required to have expert analysis of the scientific literature prepared. Decisions on these matters were further delayed by Oakhurst's limited financial resources.

80N-0146

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Recognizing that it was taking more time than expected to respond to the agency, we wrote to Dr. Ganley on July 19, 2000, September 19, 2000, and December 5, 2000 and explained that Oakhurst was in the process of preparing a response and intended to submit additional support for its petition (see enclosed).

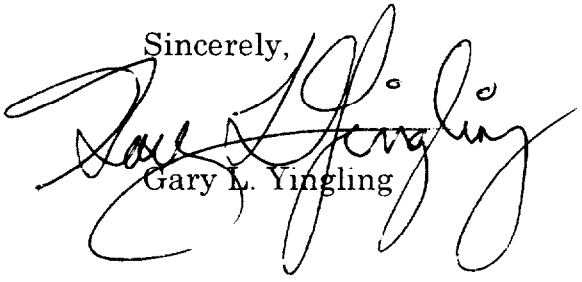
Given that the FDA had taken over 5 years to respond to Oakhurst's petition and that the company notified the agency on three separate occasions that it intended to respond to Dr. Ganley's letter, we were astonished to receive on January 4, 2001 a letter from FDA's Associate Director of Regulatory Affairs, Mr. Dennis E. Baker, formally denying Oakhurst's petition before our client had an opportunity to submit its response. While we recognize the agency's desire to close out the review of a petition that has gone on for more 5 years, that desire should not trump the agency's obligation to treat small business petitioners in a fair and equitable manner. In light of the notice that Oakhurst provided to the FDA of its intent to file a response, and the time delays associated with a small firm working with experts affiliated with academic institutions (winter holiday, examination periods, etc.), we respectfully request that FDA rescind its formal decision on this matter and provide Oakhurst with an additional 90 days to submit data and information supporting its petition.

There are no safety issues involved, and we intend to submit data establishing the intuitive notion that taste-aversive therapy using generally recognized as safe ("GRAS") food ingredients such as cayenne pepper, and safe ingredients such as denatonium benzoate, is an effective deterrent to thumbsucking and/or nailbitting. Oakhurst's original petition was under review at the FDA for over 5 years and Oakhurst's product has been in the marketplace for over 75 years. Given the lack of any safety issues, and time that has elapsed thus far, a grant of additional time to submit a response in this matter is clearly warranted.

In light of Dr. Ganley's invitation to submit additional information and the facts discussed above, we are advising our client that the docket for this matter remains open and that the FDA will review and consider the data and information that our client intends to submit within the next 90 days. If that assumption is incorrect, please notify us immediately so that we can advise our client appropriately.

Thank you in advance for your prompt consideration of this matter.

Sincerely,



Gary L. Yingling

GLY/mhh
Enclosure(s)
cc: Dennis E. Baker
Associate Commissioner for Regulatory Affairs
Dr. Charles J. Ganley
Director, Division of OTC Drug Products
James C. Morrison
CDER Ombudsman

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December 5, 2000

VIA FACSIMILE

Gary L. Yingling
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Charles J. Ganley, M.D.
Director, Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Adminstration
5600 Fishers Lane, HFD-560
Rockville, MD 20857

Re: Docket No. 80N-0146, Comment No. CP3 – Oakhurst Company

Dear Dr. Ganley:

As we noted in our letter of September 19, 2000, Oakhurst Company ("Oakhurst") is in the process of preparing a response to the Food and Drug Administration's proposed denial of the company's petition concerning thumb-sucking deterrent drug products. On behalf of our client, we have been in contact with an expert who is preparing the necessary documentation to support Oakhurst's submission. We anticipate submitting the document sometime around the first of the year.

Should you have any questions concerning this matter, please do not hesitate to contact me at (202) 496-7645.

Sincerely,

Gary L. Yingling

GLY/mhh
cc: Oakhurst Company

McKenna & Cuneo, L.L.P.

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September 19, 2000

Gary L. Yingling
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VIA FACSIMILE AND U.S. MAIL

Charles J. Ganley, M.D.
Director, Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, HFD-560
Rockville, MD 20857-0001

Re: Docket No. 80N-0146, Comment No. CP3 – Oakhurst Company

Dear Dr. Ganley:

As we noted in our letter of July 19, 2000, Oakhurst Company ("Oakhurst") intends to submit a response to the Food and Drug Administration's ("FDA's") notice that the agency intends to deny the company's petition requesting that cayenne pepper be recognized as a safe and effective ingredient in thumbsucking and nailbiting deterrent drug products. To that end, Oakhurst has been conducting an exhaustive review of the applicable scientific and medical literature and has identified a number of peer-reviewed journal articles addressing the treatment of thumbsucking and nailbiting.

Oakhurst is in the process of reviewing its research and identifying experts who can support the safe and effective use of aversive taste therapy with cayenne pepper for thumbsucking and nailbiting. The company expects to complete its research within the next few weeks and submit its comments to the agency shortly thereafter.

Should you have any questions concerning this matter, please contact me at (202) 496-7645.

Sincerely,

Gary L. Yingling by mhh

GLY/mhh
Enclosure(s)
cc: Oakhurst Company

McKenna & Cuneo, L.L.P.
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July 19, 2000

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VIA FACSIMILE AND FIRST CLASS MAIL

Charles J. Ganley, M.D.
Director, Division of OTC Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration (FDA)
5600 Fishers Lane, HFD-560
Rockville, MD 20857-0001

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

Dear Dr. Ganley:

In a letter dated May 16, 2000, you indicated your intent to recommend to the Commissioner that the FDA deny Oakhurst Company's citizen petition. The petition, filed on February 10, 1995, requested the FDA to amend the final regulation for nailbiting and thumbsucking deterrent products, codified at 21 C.F.R. § 310.536, to recognize that cayenne pepper is a safe and effective ingredient for use in aversive taste therapy products used to deter nailbiting and thumbsucking.

Your letter stated that we may file additional comments to this docket and that it was not a formal ruling on Oakhurst's petition. In that regard, we intend to submit to the FDA within the next few weeks a detailed explanation of our disagreement with the agency's denial.

Please contact me at (202) 496-7645 if you have any questions. Thank you.

Sincerely,

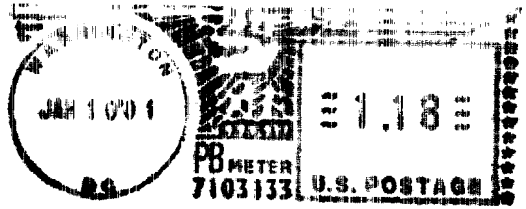
Gary L. Yingling

GLY/tl

McKenna & Cuneo, L.L.P.

Attorneys at Law

)0 K Street, N.W. ▪ Washington, D.C. 20006



FIRST CLASS MAIL

FROM

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