DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

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Robert J. Pinco
Buchanan Ingersoll
1776 K Street, N.W.
Suite 800
Washington, DC 20006-2365

Dear Mr. Pinco:

This letter is in response to your letter of July 25, 2003, requesting confidentiality of certain information contained in your Time and Extent Application (TEA) for enzacamene. After reviewing your request, the agency identified the information in your TEA that we consider confidential commercial information according to 5 U.S.C. 552(b)(4) and 21 CFR 20.61(b) and (c). During a telephone conversation on October 7, 2003, agency staff in the Division of Over-the-Counter Drug Products discussed these conclusions with you, Don Segal, and a representative of Merck KGaA (Ina Hoefgen-Muller). At that time, both parties reached agreement on the information that would be redacted from the TEA. This letter summarizes that agreement.

The agency agrees that the following information is redacted:

- Part II.B., page 4 of 10: method of synthesis and purification
- Part III.A., page 6 of 10: metric tons of Eusolex® 6300 sold to finished product manufacturers and metric tons of finished sunscreen product containing 4% Eusolex® 6300
- Attachment B: manufacturing principle
- Attachments E and F: list of product manufacturers compiled from the Göttinger Liste for 1994

The agency does not agree to redact other information identified as confidential in your July 25, 2003, letter. Specifically, the agency is not redacting the following information, because it is necessary to meet the "material time" and "material extent" requirements (§ 201(p)(2))of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(2)):

- Part III: marketing information for Eusolex® 6300 except as indicated above for Part III.A.
- Attachment G: marketing information for the five selected countries

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All sections of the TEA that we have agreed to redact will be removed from the submission prior to its being put on display at the Division of Dockets Management. If you have any questions or comments, please contact Dr. Matthew Holman of this division at 301-827-2222.

Sincerely,

Charles J. Ganley, M.D.
Director,
Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

cc: HFA-305 (Docket No. 2003N-0233)
HFD-560: Holman, Koenig/Rachanow/Ellenberg
R/D: M. Koenig: 10/08/03
Revised: M. Holman: 10/09/03
Redraft: M. Koenig: 10/15/03
Reviewed: M. Holman: 10/16/03
Endorsed:
F/T: M. Koenig