cc: HFA-305 (Docket No. 2003N-0233)
HFD-560: Holman, Koenig/Rachanow/Ellenberg
R/D: M. Koenig: 10/15/03

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

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'03 NOV 24 P1:15

Ms. Kathleen M. Sanzo
Morgan, Lewis and Bockius, LLP
1111 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Ms. Sanzo:

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 octyl triazone. 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 telephone conversations on September 4, 2003, and October 9, 2003, agency staff in the Division of Over-the-Counter Drug Products discussed these conclusions with you and Paul Shliff. 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:

- Attachment 4: manufacturing process data
- Attachments 8 – 37: global pricing and product characterization data
- Specific sales, use, and pricing data **except** for selected countries

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)):

- Specific sales, use, and pricing data for selected countries

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

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NOV 12 2003

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Sincerely,

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

2003N-0233

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