

Food and Drug
Administration
Rockville MD 20857

Karl A. Harris
Director, Regional Business Management
North America Cosmetic Division
Symrise
10 Gordon Drive
Totowa, New Jersey 07512

NOV 12

NOV 12 10:05 AM '03

Dear Mr. Harris:

This letter is in response to your letter of July 24, 2003, requesting confidentiality of certain information contained in your Time and Extent Application (TEA) for amiloxate. 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 September 3, 2003, staff in the Division of Over-the-Counter Drug Products discussed these conclusions with you and David Steinberg. Both parties agreed on the information that would be redacted from the TEA. This letter summarizes that agreement.

The agency agrees that the following information is redacted:

- Section 1, page 1: method of synthesis
- Section 1, page 3: total sales in Australia by year
- Section 1, page 4: manufacturer name
- Section 6: sales by country
- Sections 9 and 13: fax headers
- Section 13: name and address of contact at Haarmann & Reimer on letters dated June 4, 1993

The agency does not agree to redact the other information identified as confidential in your July 24, 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)):

- Section 1, page 2: the confidential paragraph, which references § 330.14(c)(2), and the cumulative total weight of the product sold in Australia for the past five years
- Section 1, page 4: the labeling information other than the manufacturer name
- Section 1 pages 5 and 6: table showing additional countries with more than 5 continuous years marketing of amiloxate
- Sections 9, 12, and 13: all information except fax headers

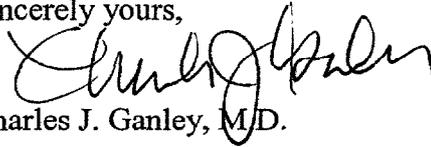
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The agency is not redacting the reference to the CIA website (Section 1, page 6), because this is a public website. The agency also is not redacting the companies listed in Section 1, pages 9 and 10, because these names appear on the labels in Section 13. Lastly, the agency is not redacting the last paragraph in Section 1, page 10, because this information is available for public review at the Division of Dockets Management.

All sections of the TEA that we have agreed to redact will be removed from the submission prior to its being put on public 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 yours,



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: 9/25/03
Revised: M. Holman: 9/29/03
Revised: G. Rachanow: 10/02/03
Redraft: M. Koenig: 10/03/03
Reviewed: G. Rachanow: 10/07/03
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Revised: M. Koenig: 10/15/03
Reviewed: M. Holman: 10/16/03
Endorsed:
F/T: M. Koenig