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2005N-0444

BKG /



Mr. David C. Steinberg
Steinberg & Associates, Inc.
16 Mershon Lane
Plainsboro, NJ 08536

Dear Mr. Steinberg:

We received your letter dated March 29, 2005, requesting that certain information be redacted from the time and extent application (TEA) that you submitted (on behalf of Symrise, Inc.) for climbazole. We agree that the information you requested be redacted represents confidential commercial information as defined in 5 U.S.C. 552(b)(4) and 21 CFR 20.61(b) and (c).

Therefore, we will redact the following information:

- Appendix 1
- In Appendix 2, the rightmost column listing the weight of climbazole sold per year in each country
- In Tables 3-1 through 3-6, the cell in each table listing the "Cumulative total number of dosage units sold for each dosage form"

In place of the information redacted from tables 3-1 through 3-6, we will insert a table identical to the one you submitted on March 29, 2005, listing regional marketing data. This table will be designated Table 3-7 and will follow immediately after table 3-6 in the TEA. FDA is making this replacement in accordance with your March 29, 2005 letter.

All redacted information will be removed from the TEA prior to its being placed on public display at the Division of Dockets Management. If you have any questions or comments regarding this matter, please contact Dr. Michael Koenig at 301-796-2090.

Sincerely,

Charles J. Ganley, M.D.

Director,

Office of Nonprescription Products

Center for Drug Evaluation and Research