



Lisa Navarro, Ph.D., D.A.B.T.
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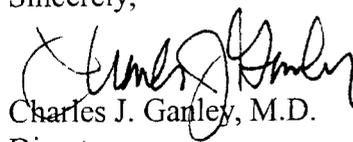
Dear Dr. Navarro:

We are writing in response to the time and extent applications (TEAs) that you submitted on April 11, 2005, for the sunscreens bisoctrizole and bemotrizinol. In your TEAs, you marked certain information as "Confidential Business Information." This information is enclosed within purple or blue boxes and we agree that it 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 in the two TEAs prior to their being placed on public display at the Division of Dockets Management.

- Section 2.7: information enclosed within the purple boxes
- Table 7 in Section 3.4: information enclosed within the purple box except:
 1. the cells identifying the row "TOTAL (7 countries)" and the column "Total Volume 2000-2004 (KGS.)"
 2. the total volume of bisoctrizole/bemotrizinol sold in the 7 selected countries between 2000 -2004
- Table 8 in Section 3.4: information enclosed within the purple box except:
 1. the cells identifying the row "TOTAL (7 countries)" and the column "Total Number of Units (x 1000) 2000-2004"
 2. the estimated total number of units sold in the 7 selected countries between 2000 - 2004
- Table 9 in Section 3.4: information enclosed within the purple box except:
 1. the cells identifying the row "TOTAL (7 countries)" and the column "Total Application Number (Million) 2000-2004"
 2. the estimated total number of applications sold in the 7 selected countries between 2000-2004
- Appendix II: information enclosed within blue boxes

If you have any questions or comments regarding this matter, please contact Dr. Michael Koenig at 301-796-2090.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles J. Ganley". The signature is fluid and cursive, with the first name "Charles" being the most prominent.

Charles J. Ganley, M.D.

Director,

Office of Nonprescription Products

Center for Drug Evaluation and Research