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2005N-0445

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OCT 31

Food and Drug Administration  
Rockville MD 20857

Dr. Lisa Navarro  
Ciba Specialty Chemicals Corporation  
Home and Personal Care Business Line  
4090 Premier Drive  
High Point, NC 27265

Dear Dr. Navarro:

We received your letter dated May 5, 2005, requesting that certain information be redacted from the time and extent application (TEA) that you submitted for triclosan used in the treatment of acne. 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:

- Section 1.2.7 (other than the title)
- Tables 2 and 3 in Section 2.1.1 (other than the titles)
- Table 4 in Section 2.2: specific country/region estimates of units sold by year

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