



Ciba

13 February 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Resources
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Via Next Day Courier
Return Receipt Requested

Subject: Addendum to Citizen Petition of 2/11/02: OTC Docket 75N-183H (triclosan)

On February 11, 2002, Ciba Specialty Chemicals Corporation ("Ciba"), Home and Personal Care Segment submitted a Citizen's Petition under 21 CFR § 10.30 requesting the Commissioner of Food and Drugs to re-open the administrative record associated with the OTC Tentative Final Monograph for Health-Care Antiseptic Drug Products as proposed under Subpart E of 21 CFR Part 333 (59 FR 31402 and 59 FR 58799) to allow for the submission and evaluation of additional efficacy and safety data, contained herein, supporting the Category I efficacy and safety status of triclosan at concentrations up to 1 percent.

The attached Study: "*Efficacy Evaluation Of Triclosan Hand washing Products For Use In The Health Care Environment, October 2001*" (APPENDIX B (ii)) was inadvertently omitted from that submittal. Ciba formally requests that the FDA include this study as part of the submission of February 11, 2002 and incorporate this report into OTC Docket 75N-183H (triclosan).

As stated previously, Ciba believes that triclosan is safe (for both short- and long-term use) and efficacious at concentrations up to 1 percent and should be classified as a Category IE and IS active ingredient for both short- and long-term use under FDA's Monograph for antimicrobial health-care and consumer/food-handler products.

We apologize for any inconveniences incurred as a result of this correction and once again would like to thank the Agency for evaluating the enclosed data under OTC Docket 75N-183H. Please contact the undersigned at (336) 801-2493 if there are any further questions or comments regarding this petition.

Sincerely,

Carl David D'Ruiz, MPH
Head, Product Stewardship & Regulatory Affairs
Home and Personal Care Segment

Attachments

75N-183H

SUPS

Desk copy:

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OTC Docket No. 78N-0038

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