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1001 G STREET, N. W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001  
TEL. 202.434.4100  
FAX 202.434.4040  
WWW.KHLAW.COM

WRITER'S DIRECT ACCESS

**Frederick A. Stearns**  
(202) 434-4288  
stearns@khlaw.com

August 13, 2004

**Via Hand Delivery**

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. 2004N-0050; Submission of Safety and Effectiveness Data for Piroctone Olamine**

On behalf of Clariant GmbH, we hereby submit three copies of the enclosed safety and effectiveness information to support the use of piroctone olamine (tradename Octopirox®) as a single active ingredient in topical OTC products to relieve or control dandruff, seborrheic dermatitis, and/or psoriasis, consistent with the final OTC monograph for these products found at 21 C.F.R. Part 358, Subpart H (21 C.F.R. §§ 358.701- .750). The proposed concentrations are 0.05% to 0.5 % in leave-on and 0.1% to 1.0 % in rinse-off dosage forms.

Piroctone olamine was the subject of a Time and Extent Application (TEA), through which FDA found the ingredient and its proposed use eligible for consideration in the OTC drug monograph system. 69 *Fed. Reg.* 7652 (February 18, 2004). The deadline for the submission of safety and effectiveness data was extended to August 16, 2004. 69 *Fed. Reg.* 28932 (May 19, 2004).

Thank you for your consideration of these materials. Please feel free to contact me if you have any questions or need additional information.

Sincerely,



Frederick A. Stearns

Enclosures

- Safety and effectiveness information (Vol. 1)
- Supporting references (Vols. 2 - 6)

cc: Michael L. Koenig, Ph.D. (FDA) (via email) (cover letter only)

WASHINGTON, D.C.

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