

WRITER'S DIRECT ACCESS

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October 15, 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, on August 13, 2004, we submitted 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.

This letter confirms that Clariant does not view the reports included in the safety and effectiveness submission to be confidential. Clariant does not object to this information being placed in the docket.

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

Sincerely,



Frederick A. Stearns

cc: Michael L. Koenig, Ph.D. (FDA) (via email)  
Keith J. Olin (FDA) (via email)

**2004N-0050**

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