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WRITER'S DIRECT ACCESS

April 16, 2004

Frederick A. Stearns
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Via FedEx

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

Re: Docket No. 2004N-0050; Request for Extension of Time to Submit Safety and Effectiveness Data for Piroctone Olamine

On behalf of Clariant GmbH, we hereby request a 90-day extension of the deadline to respond to the call for safety and effectiveness data concerning Piroctone Olamine, announced at 69 *Fed. Reg.* 7652 (February 18, 2004). The original deadline is May 18, 2004; Clariant requests that this be extended to August 16, 2004.

Clariant requires additional time to compile the data necessary to document that piroctone olamine is generally recognized as safe and effective as an over-the-counter (OTC) dandruff control active ingredient. By extending the deadline, FDA will allow the Company to assemble a comprehensive submission for this ingredient.

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

Sincerely,

Frederick A. Stearns

Frederick A. Stearns

cc: Michael L. Koenig, Ph.D. (FDA) (via facsimile)

2004N-0050

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