

November 7, 2001

Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Docket No. 98N-0337 Comment Nos. APP11 & APP12

APPLICATION FOR DEFERRAL (REQUEST FOR WITHRAWAL)

Re:

Withdrawal of Request for Deferral from 21 CFR 201.66 (OTC Drug Product

Labeling)

Subject:

L. Perrigo Company (Perrigo)

Suphedrine Cold & Cough Liquid-Filled Capsules (Perrigo code 080)

Day Time Liquid-Filled Capsules (Perrigo product code 389)

Pursuant to 21 CFR 201.66(e) Perrigo requested a Deferral from 21 CFR 201.66 for its Suphedrine Cold & Cough Liquid-Filled Capsule over-the-counter drug product (Perrigo product code 080) and Day Time Liquid-Filled Capsules (Perrigo product code 389). The requests were sent to Docket No. 98N-0337 and were dated August 9, 2001. Perrigo requested that the Food and Drug Administration defer compliance until Exemption Requests dated October 6, 2000 had been answered regarding the use of the phrase "May contain" in the inactive ingredients section of the product label.

On November 6, 2001 Perrigo received a response to the Exemption Requests from the Food and Drug Administration. At this time, Perrigo requests the withdrawal of both Deferral requests dated August 9, 2001 regarding Suphedrine Cold & Cough Liquid-Filled Capsules (Perrigo code 080) and Day Time Liquid-Filled Capsules (Perrigo product code 389).

If there are any questions concerning this request, please contact me by phone at (616) 673-7595 or fax at (616) 673-7655. Thank you for your attention to this matter.

Sincerely,

L. PERRIGO COMPANY

David Jespersen

Director of Technical Affairs

98N-0337

WD~/

515 Eastern Avenue Allegan, Michigan 49010 (616) 673-8451 From: David Jespersen (616)673-7595 Perrigo Company 502 Eastern Avenue Plant 6 Allegan, MI, 49010



To: Docket no. 98N-0337 (301)827-2222 Food and Drug Administration 5630 Fishers Lane, Room 1061

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