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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT 23 2003

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Charles J. Raubichek, Esq.
Frommer Lawrence & Haug LLP
745 Fifth Ave.
New York, NY 10151

Re: Docket No. 03P-0160/CP1

Dear Mr. Raubichek:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on April 16, 2003. Your petition requests that the Agency refuse to approve the new drug application (NDA) submitted by L. Perrigo Company under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) for loratadine tablets, 10 milligrams, because the NDA (1) is ineligible for approval under this section and (2) is subject to a 30-month stay on approval.

FDA has not made a decision on your petition because approval of Perrigo's NDA is stayed under section 505(c)(3)(C) of the Act for 30 months or until the issuance of a court decision in Schering Corp. v. Perrigo Co. (No. 02-CV-5718, D.N.J.), whichever comes first. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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