



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 15 2002

Robert C. Seidman, PharmD, MPH
Chief Pharmacy Officer
WellPoint Health Networks
21555 Oxnard Street
Woodland Hills, CA 91367

Re: Docket No. 02P-0163/CP1

Dear Dr. Seidman:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your petition dated April 15, 2002, requesting that the FDA exempt Clarinex (desloratadine) from the prescription dispensing requirements thereby switching Clarinex to over-the-counter (OTC) status.

FDA has been unable to reach a decision on your petition because it raises issues that require additional review and analysis by the Agency. 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 yours,

for Janet Woodcock, M.D.
Director

Center for Drug Evaluation and Research

02P-0163

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