

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUL 08, 2004

FDA CONTROL NUMBER: 04 3486

TRACER #: **OS #:**

DATE OF CORRESPONDENCE: 06/14/04

DATE INTO FDA: 06/15/04

TO: LESTER M CRAWFORD, ACTING COMMISSIONER OF THE FOOD AND DRUG
ADMINISTRATION

FROM: WOODROW MYERS, WELLPOINT
ROBERT SEIDMAN, WELLPOINT

SYNOPSIS: WRITES TO REQUEST THAT THE FDA ACT ON WELLPOINT'S CITIZEN
PETITION (98P-0610/CP1) TO SWITCH CETIRIZINE (ZYRTEC),
FEXOFENADINE (ALLEGRA) AND DESLORATADINE TO OTC STATUS.

LEAD OFFICE: HFD-1

HOME OFFICE: HF-40

CONTACT/PHONE#: CAPRI R MCCLENDON 301-827-5903

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HF-40 LA JUANA D CALDWELL
HF-40 WALTER D OSBORNE
HF-40 ELIZABETH A CLARKE

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
----- HFD-1	----- PREPARE DIRECT REPLY	----- 07/17/04
REMARKS: PLEASE FORWARD COPY OF RESPONSE TO CAPRI MCCLENDON AT HF-40. THANK YOU.		



06-15-04A11:26 RCVD

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Woodrow A. Myers, Jr., MD, MBA
Executive Vice President
Chief Medical Officer

June 14, 2004

Dr. Lester M. Crawford
Commissioner
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Room 1471, Mail Stop HF-1
Rockville, MD 20857

Re: Citizen's Petition 98P-0610/CP1

Dear Commissioner Crawford:

A joint meeting of the FDA Non-Prescription Drugs Advisory Committee and Pulmonary-Allergy Drug Advisory Committee was held on May 11, 2001 to consider a Citizen's Petition submitted by WellPoint. At that time, the Committees concluded that loratadine (Claritin), cetirizine (Zyrtec), and fexofenadine (Allegra) had a safety profile acceptable for over-the-counter marketing and could be safely used without a learned intermediary. According to the Durham-Humphrey Amendment to the Federal Food, Drug, and Cosmetic Act, a drug is expected to be made available without a prescription if, by following the labeling, consumers can use it safely and effectively without professional guidance. Loratadine became an OTC drug in the fall of 2002 but the FDA has not yet acted on the WellPoint Citizen's Petition to switch cetirizine and fexofenadine to OTC status. This letter asks again that cetirizine and fexofenadine be switched to OTC status. In addition, we seek to have desloratadine, an active metabolite of loratadine, switched to OTC status.

WellPoint believes that safer, equally efficacious second generation antihistamines should be made available to the public without the requirement of a physician visit and prescription. Movement to OTC status will increase ease of access and lower cost to the consumer by obviating the need for the expense of a physician visit. Movement of the non-sedating antihistamines to OTC status will also result in a price reduction. The price of Claritin dropped from \$3/pill to \$0.10/pill when it became an OTC generic drug. Due to significant OTC competition, a significant drop in price can be anticipated for the other second generation antihistamines. Removing these antihistamines from prescription drug status also helps health care companies such as WellPoint to provide affordable access to the next generation of biological drugs under FDA review.

We appreciate your attention to this important matter and await your reply.

Respectfully,

Woodrow A. Myers Jr. MD MBA
Executive Vice President & Chief Medical Officer

Robert Seidman PharmD MPH
Vice President & Chief Pharmacy Officer

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