



TRANSMITTED BY FACSIMILE

Ms. Rita A. Wittich
Vice-President, Worldwide Regulatory Strategy
Pfizer Inc.
Regulatory Affairs
235 East 42nd Street
New York, NY 10017

RE: NDA# 19-835
Zyrtec (cetirizine HCl) Tablets
MACMIS ID#: 10817

Dear Ms. Wittich:

This letter objects to Pfizer Inc.'s (Pfizer) dissemination of a violative direct-to-consumer (DTC) television (TV) broadcast advertisement (ad) for Zyrtec Tablets. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this Zyrtec Pollen Count Banner/Billboard TV ad as part of its monitoring and surveillance program. The ad (submitted on April 2, 2002, via Form FDA 2253) was broadcast on "The Weather Channel Pollen Count Report." DDMAC has concluded that the Zyrtec TV ad is lacking in fair balance or otherwise misleading, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations.

Lacking in Fair Balance or Otherwise Misleading

This Zyrtec TV ad features the Zyrtec name and/or logo as sponsor of the Weather Channel Pollen Count Report. An announcer states "Today's pollen count is brought to you by Zyrtec. Ask your doctor about Zyrtec" while the Zyrtec "billboard" logo is displayed. Immediately thereafter, the Zyrtec logo is presented as a banner embedded in the Weather Channel graphic that displays pollen levels for various seasonal allergens (tree or grass pollen, ragweed, and mold spores) in specific cities. These uses of the Zyrtec logo and name as part of this pollen report clearly represent or suggest that Zyrtec is used to treat seasonal allergies. However, the ad does not disclose any risk information about the prescription drug as required by the Act and FDA regulations.

Under 21 USC 352 (n), all prescription drug ads must contain a true statement of information in brief summary relating to side effects, contraindications, and effectiveness. The prescription drug advertising regulations provide that TV broadcast ads shall include (1) information relating to the major side effects and contraindications of the advertised drug in the audio or audio and visual presentation, and (2) unless "adequate provision" is made for the dissemination of the approved product labeling (package insert or "PI") in connection with the broadcast, a brief summary of all necessary information related to side effects and contraindications (21 CFR 202.1(e)(1)).

DDMAC concludes that the Zyrtec Pollen Count banner/billboard TV ad lacks fair balance or is otherwise misleading because it failed to provide information relating to the major side effects and contraindications, and to make adequate provision for the dissemination of the PI or inclusion of the brief summary of information related to side effects and contraindications in conjunction with the ad.

Requested Action

Pfizer should immediately discontinue this and all other promotional materials and activities for Zyrtec that contain the same or similar presentations. We request that Pfizer respond in writing with its intent to discontinue such use. Please provide your written response no later than May 14, 2002. This response should list similarly violative materials with a description of the method for discontinuation and the discontinuation date.

Your response should be directed to me by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857.

In all future correspondence on this matter, please refer to MACMIS ID# 10817 as well as the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin, JD
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joan Hankin

4/30/02 03:24:33 PM

ZYRTEC
Zyrtec is a prescription medicine used to treat allergies. It is available in tablet and syrup forms. Zyrtec is a second-generation antihistamine that works by blocking histamine, a natural substance in your body that causes allergy symptoms. Zyrtec is used to relieve symptoms of seasonal allergies (hay fever) and perennial allergies. Common symptoms include sneezing, runny nose, itchy eyes, and itchy throat. Zyrtec is generally well-tolerated, but may cause drowsiness or dry mouth. It is important to follow your doctor's instructions when taking Zyrtec. Zyrtec is available in the United States and other countries. For more information, visit the Zyrtec website or call 1-800-4-zyrtec.

1-800-4-zyrtec

Weather Channel - Pollen Count

Announcer Copy - Note to Announcer, Zyrtec is pronounced: ZUR-TEK

Today's Pollen count is brought to you by Zyrtec. Ask your doctor about Zyrtec.

WEATHER CHANNEL

Pollen Levels

none

very high

As reported in Atlanta on January 14, 2002.

Tree Pollen

HIGH

Grass Pollen

LOW

Ragweed

MODERATE

Mold Spores

ZYRTEC[®]
cetirizine HCl
1-800-4-zyrtec