



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 9 2000

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 50-710
Zithromax (azithromycin for oral suspension)
MACMIS ID#: 9490

Dear Ms. Wittich:

This letter addresses Pfizer Inc.'s (Pfizer) dissemination of a television broadcast "reminder" advertisement for Zithromax (azithromycin for oral suspension) (ZC316A99). The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed this advertisement and concluded that it is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the drug product. The focus of graphics in the reminder advertisement emphasizes the use of Zithromax oral suspension in children, along with the audio statements "Pfizer brings parents the letter "Z" for Zithromax. More information about Zithromax is just a click away at www.pfizerkids.com" (and accompanying graphic of the website www.pfizerkids.com). Therefore, the advertisement in total, with the graphics and verbal statements, make a representation about use of Zithromax oral suspension in a specific patient population.

Pfizer should immediately cease using this television advertisement and all other promotional materials for Zithromax oral suspension that contain the same or similar claims or presentations. We should receive your written response no later than November 27, 2000, and it should list similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

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

Ms. Rita A. Wittich
Pfizer Inc.
NDA#: 50-710

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DDMAC reminds Pfizer that only written communications are considered official. In all future correspondence, regarding this matter, please refer to MACMIS ID# 9490 in addition to the NDA number.

Sincerely,

/S/

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

PRODUCT Zithromax
MARKET New York
PROGRAM Sesame Street
CODE # 0002-02882
TITLE Bringing Parents The Letter Z

LENGTH :15
STATION WNET
DATE 02/10/00
TIME 8:03 AM



(MUSIC/SINGING IN) FEMALE ANNCR:
Pfizer.



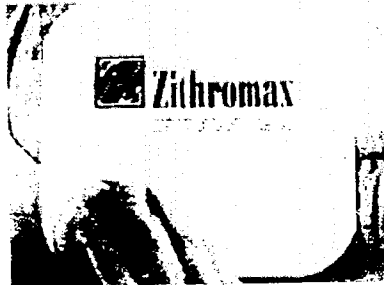
(SFX: KIDS LAUGHING IN & OUT)



(MUSIC)



Pfizer brings parents the letter Z



for Zithromax. More information
about Zithromax (SFX: CLICK)

SUPER: (SZITHROMYCIN* FOR ORAL SUSPENSION)



is just a click away. Pfizer. Life
is our life's work. (SINGING/MUSIC
OUT)

ALSO AVAILABLE ON VIDEO CASSETTE