



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

NOV 14 2000

Jerome M. Prah
Associate Director
Regulatory Affairs
G.D. Searle & Co.
4901 Searle Parkway
Skokie, Illinois 60077

RE: NDA 20-998
Celebrex (celecoxib) capsules
MACMIS ID #9514

Dear Mr. Prah:

This letter refers to G.D. Searle & Co.'s (Searle) submission of direct-to-consumer (DTC) promotional materials under cover of Form FDA 2253 for Celebrex (celecoxib) capsules. This submission included a 60-second "full product" broadcast television (TV) advertisement and a 15-second "reminder" TV advertisement, identified as CE20243T and CE20567T, respectively. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these broadcast advertisements and has concluded that they are in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Our specific objections follow:

Full Product Advertisement

- The 60-second "full product" TV advertisement is misleading because the totality of the images, the music, and the audio statements that you present overstate the efficacy for Celebrex. For example, supers such as "Bill--arthritic knees," various multiple physical activities portrayed by arthritis patients (such as rowing a boat and riding a scooter), the soundtrack "Celebrate, Celebrate. Do what you like to do," and the audio statement, "Powerful 24-hour relief from osteoarthritis pain and stiffness," collectively suggest that Celebrex is more effective than has been demonstrated by substantial evidence.

Reminder Advertisement

- Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic representations or suggestions relating to the drug product. Your advertisement is misleading because the audio statement, "Celebrate, Celebrate. Do what you like to do," makes a representation or suggestion about the efficacy of Celebrex.

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Requested Actions

You should immediately cease distribution of these violative broadcast TV advertisements and other similar promotional materials for Celebrex that contain the same or similar claims or presentations. You should submit a written response, on or before, November 29, 2000, describing your intent and plans to comply with the above. Your letter should also include a list of materials discontinued and the date on which these materials were discontinued.

You should direct your response to me by facsimile at (301) 594-6771, or by writing at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official.

In all future correspondence regarding this matter, please refer to the MACMIS # 9514 and the NDA number.

Sincerely,

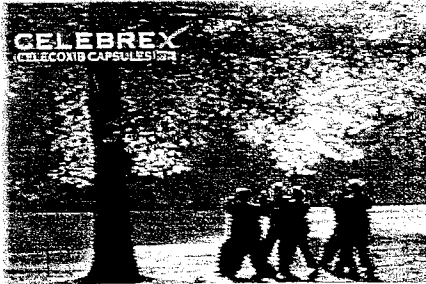
/S/

Spencer Salis, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications



TITLE: "City Park"
LENGTH: :60

PRODUCT: Celebrex
COMPANY: Pharmacia/Pfizer



AVO: If you have arthritis pain, there's reason to celebrate. It's Celebrex.
SUPER: Celebrex Logo



SONG: CELEBRATE, CELEBRATE.
SUPER: Ann - arthritic shoulders



SONG: DO WHAT YOU LIKE TO DO.
SUPER: Bill - arthritic knees



AVO: Powerful 24-hour relief from osteoarthritis pain and stiffness.



AVO: Celebrex,



AVO: the first arthritis medicine that targets only the COX-2 enzyme.
SUPER: Dave - arthritic hands



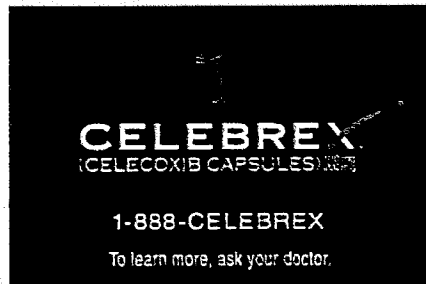
SONG: CELEBRATE, CELEBRATE. DO WHAT YOU LIKE TO DO.
SUPER: Liz - arthritic back



AVO: Celebrex should not be taken if you've had aspirin-sensitive asthma or allergic reactions due to aspirin or other arthritis medicines or certain drugs called sulfonamides. In rare cases, serious stomach problems such as bleeding can occur without warning. Tell your doctor if you have kidney or liver problems. SUPER: Celebrex.com
SUPER: Celebrex should not be taken in late pregnancy



SONG: CELEBRATE, CELEBRATE. DO WHAT YOU LIKE TO DO.
SUPER: See our ad in Health magazine



AVO: Ask your doctor about Celebrex. Celebrex. The number one selling brand of prescription arthritis medicine.
SUPER: #1
SUPER: Celebrex Logo
SUPER 1-888-CELEBREX
SUPER: To learn more, ask your doctor about Celebrex.



SONG: CELEBRATE, CELEBRATE.



SONG: DO WHAT YOU LIKE TO DO.



TITLE: "City Park"
LENGTH: :15

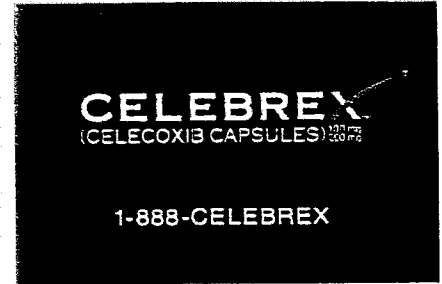
PRODUCT: Celebrex
COMPANY: Pharmacia/Pfizer



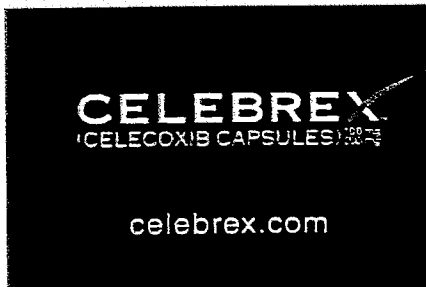
SONG: CELEBRATE, CELEBRATE.



SONG: DO WHAT YOU LIKE TO DO.



AVO: Ask your doctor if
SUPER: Celebrex Logo
SUPER 1-888-CELEBREX



AVO: Celebrex is right for you.
SUPER: Celebrex Logo
SUPER: Celebrex.com



SONG: CELEBRATE, CELEBRATE.



SONG: DO WHAT YOU LIKE TO DO.