



AUG 24 2000

TRANSMITTED VIA FACSIMILE

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

Re: **NDA 19-908**
Ambien (zolpidem tartrate) CIV
MACMIS ID #9272

Dear Mr. Prah:

This letter addresses G.D. Searle & Co.'s (Searle) dissemination of a 15 second television broadcast "reminder" advertisement for Ambien (zolpidem tartrate) CIV. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this advertisement as part of its monitoring and surveillance program and has concluded that the advertisement 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. Ambien is indicated for the short-term treatment of insomnia. The reminder advertisement presents graphics of the sun and the earth going from night to day, a flower closing and opening, and the Ambien tablet falling on a sheet or pillow, together with the verbal statement "the rhythm of life." Thus, the advertisement in total, with the graphics and verbal statement, makes a representation about the product.

DDMAC requests that Searle immediately cease using this advertisement and all other promotional materials for Ambien that contain the same or similar claims or presentations. Searle should submit a written response to DDMAC, on or before September 1, 2000, describing its intent and plans to comply with the above. In its letter to DDMAC, Searle should include a list of all promotional materials that were discontinued, and the discontinuation date.

Jerome [unclear]
G.D. Searle & Co.
NDA 19-908

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Searle should direct its response to Lisa Stockbridge, Ph.D. or Leah Palmer, Pharm.D. by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to MACMIS #9272 and NDA 19-908.

Sincerely,

/s/

Leah Palmer, Pharm.D.
Branch Chief
Division of Drug Marketing,
Advertising, and Communications