DEPARTMENT OF HEALTH & HUMAN SERVICES

FOI

Food and Drug Administration
Rockville MD 20857

DEC - 9 1998

TRANSMITTED VIA FACSIMILE

Joseph S. Sonk, Ph.D.
Senior Director, Women's Healthcare Products
U.S. Drug Regulatory Affairs
Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299

RE: **NDA#** 20-683
Alesse (levonorgestrel and ethinyl estradiol) Tablets
MACMIS ID# 7364

Dear Dr. Sonk:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Alesse, that were submitted by Wyeth-Ayerst Laboratories (Wyeth) on Form FDA 2253, that are considered to be false or misleading, and in violation of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder. These materials include two flashcards (ID # 74821-01 and 74913-00).

Specifically, DDMAC objects to the presentation that Alesse is *the* 20 microgram oral contraceptive that offers low discontinuation rates, favorable tolerability, and high performance. This presentation implies that Alesse is the only low dose oral contraceptive that offers these benefits. Furthermore, since Alesse is not the only 20 microgram oral contraceptive on the market, this presentation implies, without adequate substantiation, that these benefits are comparatively better for Alesse than with the other low dose oral contraceptives.

DDMAC requests that Wyeth immediately discontinue these and any other promotional materials that have the same or similar messages. Wyeth should respond, in writing, with its intent to comply with DDMAC's request by December 23, 1998. This response should include a list of all violative materials that will be discontinued and a description of Wyeth's plan for addressing this issue.

If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all future correspondence regarding this matter, please refer to the MACMIS ID # 7364 in addition to the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications