DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

MAY 19 1997

TRANSMITTED VIA FACSIMILE

Joan E. Barton
Associate Director, Regulatory Affairs
Wyeth-Ayerst Laboratories
P.O. Box 8299
Philadelphia, PA 19101-8299

RE: NDA 20-756
Crinone (progesterone) Gel
MACMIS 5419

Dear Ms. Barton:

Reference is made to Wyeth-Ayerst's (Wyeth) press release submitted to the Division of Drug Marketing, Advertising and Communications (DDMAC) on the evening of May 13, 1997, for Crinone (progesterone) Gel. We also refer to the telephone conversation on the morning of May 14, 1997, in which I told you that DDMAC would attempt to give you comments on the press release before 1:00 PM (Eastern Standard Time). I told you that I had concerns about at least one presentation before I had finished the first read of the press release.

On or about 10:30 AM on May 14, 1997, Wyeth published the press release before receiving DDMAC's comments. DDMAC has obtained a copy of the press release from the internet and finds it to be misleading and in violation of the Federal Food, Drug, and Cosmetic Act for the following reasons:

1. Any comparative claims to suppositories or intramuscular injection are misleading without adequate substantiation. Thus, Crinone cannot be presented as "more convenient", "easier", "more comfortable", etc. without adequate supporting evidence. Similarly, the headline "More Convenient Therapy Alternative Without the Pain of Injection or Mess of Suppositories" is considered misleading as are claims that Crinone is tidier, easier, or more consistent.

2. The Agency is not aware of adequate substantiation for the claim that Crinone offers an advantage over intramuscular progesterone because it has a direct effect on the endometrium despite

substantially lower blood levels. Thus, this claim is considered to be unsubstantiated and misleading.

In order to address these objections, DDMAC suggests that Wyeth take the following actions:

1. Immediately remove the violative press release(s) from the public domain.

2. Provide DDMAC, in writing, with Wyeth's intent to comply with number one above.

Wyeth's response should be received no later than May 29, 1997. 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. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5419 in addition to the NDA number.

Sincerely,

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