DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 26 1998

TRANSMITTED VIA FACSIMILE

Albert Mayo
Director, Regulatory Affairs
Organon
375 Mt. Pleasant Avenue
West Orange, NJ 07052

RE: NDA 20-582
Follistim (follitropin for injection)
MACMIS #6784

Dear Mr. Mayo:

Reference is made to Organon's June 12, 1998, Form FDA 2253 submission to the Division of Drug Marketing, Advertising and Communications (DDMAC) for Follistim (follitropin for injection). This submission included a brochure entitled "Some Cloning is Questionable" (ID# OR4C290) that is in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations because the risk information is not presented in a prominence and readability that is reasonably comparable to the presentation of information relating to the effectiveness of the drug.

Specifically, DDMAC finds the brochure to be lacking in fair balance because the risk information appears in small print (the same point size as the references) on the back page of the brochure. The risk information is further obscured by an attached BRC card.

In order to address this objection, DDMAC requests that Organon immediately discontinue the use of this brochure and any other materials with the same or similar issues. Organon should provide DDMAC, in writing, with its intent to comply with this request no later than July 10, 1998.

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 #6784 in addition to the NDA number.

Sincerely,

/S/

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