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Application Number: NDA 20582/S001

APPROVAL LETTER

NDA 20-582/S-001

NOV 18 1998

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

Dear Mr. Mayo:

Please refer to your supplemental new drug application dated May 18, 1998, received May 19, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim™ (follitropin beta for injection).

We acknowledge receipt of your submissions dated November 4 and 16, 1998.

This supplemental new drug application provides for changing the diluent from 0.45% Sodium Chloride to Sterile Water for Injection, USP.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

ISI 11/18/98

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader for the
Division of Reproductive and Urologic Drug Products,
(HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:

Archival NDA 20-582/S-001
HFD-580/Div. Files
HFD-580/D.Moore
HFD-580/LRarick/MMann/MRhee/VJarugula/AParekh/TRumble
HFD-510/DWu
HFD-95/DDMS
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: tfr/November 17, 1998/nda/suppl/20582s01ap.doc

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Concurrence:

TRumble 11.17.98/DWu, MRhee, VJarugula, AParekh, MMann, LRarick 11.17.98

APPROVAL (AP)

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