

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number: NDA 20582/S002**

**APPROVAL LETTER**

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CF

NDA 20-582/S-002

MAR 26 1999

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

Dear Mr. Mayo:

Please refer to your supplemental new drug application dated November 20, 1998, received November 27, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Follistim® (follitropin beta for injection).

We note that this supplement was submitted as a 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

This supplemental new drug application provides for an alternate piece of equipment to wash, siliconize, sterilize, and dry the stoppers used for the manufacture of drug product. Your submission stated January 14, 1999, as the implementation date for these changes.

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 Ms. Eufrecina DeGuia, Regulatory Project Manager, at 301-827-4260.

Sincerely,

/S/ 3/26/99

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

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DISTRICT OFFICE

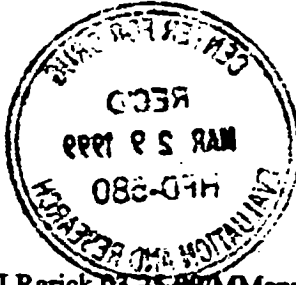
Drafted by: ed/March 22, 1999

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Concurrences:

TRumble 03.23.99/MRhee 03.24.99/LRarick 03.25.99/MMann 03.26.99

APPROVAL (AP)



*Ede Guis*