

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20582/S002

CORRESPONDENCE



Food and Drug Administration
Rockville MD 20857

NDA 20-582/S-002

DEC - 4 1998

Organon Inc.
375 Mt. Pleasant Avenue
West Orange, New Jersey 07052

Attention: Albert P. Mayo
Director, Regulatory Affairs

Dear Mr. Mayo:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Follisim[®] (follitropin beta for injection)

NDA Number: 20-582

Supplement Number: S-002

Date of Supplement: Novemeber 20, 1998

Date of Receipt: Novemeber 27, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on January 26, 1999, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation II
Attention: Document Control Room 17B-20
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

for Lana Pauls
Chief, Project Management Staff
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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cc:

Original NDA 20-582/S-002

HFD-580/Div. Files

HFD-580/CSO/D. Moore

SUPPLEMENT ACKNOWLEDGEMENT

Listing of NDA's this submission is also being sent to:

- ✓ NDA No. 16-750 Cortrosyn® (cosyntropin) for Injection }
Sent to: Division of Metabolism and Endocrine Drug Products (HFD-510)
- ✓ NDA No. 13-132 Deca-Durabolin® (nandrolone decanoate injection, USP)
Sent to: Division of Metabolism and Endocrine Drug Products (HFD-510)
580
- NDA No. 20-328 Humegon® (menotropins for injection, USP)
Sent to: Division of Reproductive and Urologic Drug Products (HFD-580) scm/003
- NDA No. 18-776 Norcuron® (vecuronium bromide) for Injection
Sent to: Division of Anesthetic, Critical Care & Drug Addiction Products (HFD-170)
- NDA No. 17-692 Pregnyl® (chronic gonadotropin for injection, USP)
Sent to: Division of Reproductive and Urologic Drug Products (HFD-580)
- NDA No. 17-398 Regonol® (pyridostigmine bromide injection, USP)
Sent to: Division of Anesthetic, Critical Care & Drug Addiction Products (HFD-170)
- NDA No. 89-624 Reversol® (edrophonium chloride injection, USP)
Sent to: Office of Generic Drug Products (HFD-600)
- ✓ NDA No. 80-997 Succinylcholine Chloride Injection, USP
Sent to: Office of Generic Drug Products (HFD-600)
- NDA No. 20-214 Zemuron™ (rocuronium bromide) Injection
Sent to: Division of Anesthetic, Critical Care & Drug Addiction Products (HFD-170)