CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020280/S008

Trade Name: GENOTROPIN

Generic Name: SOMATROPIN (rDNA ORIGIN) FOR INJECTION

Sponsor: PHARMACIA ANDUPJOHN, INC.

Approval Date: 10/31/97

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APPLICATION: 020280/S008

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Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)				
Administrative Document(s)	X			
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Application Number: 020280/S008

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-280/S-008

OCT 31 1997

Pharmacia and Upjohn Inc.
Attention: Susan M. Mondebaugh, Ph.D.
Director, Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001-0199

Dear Dr. Mondebaugh:

Please refer to your supplemental new drug application dated November 1, 1996, received November 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin™ [somatropin (rDNA origin) for injection].

We acknowledge receipt of your submissions dated December 4, 1996, April 30, March 13, May 16, June 2, July 2 and 10, August 14, 15, and 18, and October 31 (fax), 1997. The User Fee goal date for this application is November 4, 1997.

The supplemental application provides for the additional use of Genotropin for long-term replacement therapy in adults with growth hormone deficiency as demonstrated by an appropriate GH stimulation test.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission (fax) dated October 31, 1997. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted (fax) on October 31, 1997.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 20-280/S-008. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-

up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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, please contact Michael F. Johnston, R.Ph., Project Manager, at (301) 827-6423.

Sincerely yours,

/S/ 10/31/97

APPEARS THIS WAY
ON ORIGINAL

Solomon Sobel, M.D.
Director
Division of Metabolic and Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc: Original NDA 20-280
HFD-510/Div. files
HFD-510/SSobel/EGalliers/GFleming/SMalozowski/RSteigerwalt/DHertig/
WBerlin/SMoore/MJohnston
HFD-870/HAhn/RShore
HFD-715/Nevius
HFD-002/ORM (with labeling)
HFD-102/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.
HFI-20/Press Office (with labeling)

Drafted by: Miohnston10.XX.97/

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.