

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-863/S002

Trade Name: Geref

Generic Name: sermorelin acetate for injection

Sponsor: Serono Laboratories, Inc.

Approval Date: May 28, 1991

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APPLICATION NUMBER:
NDA 19-863/002

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Reviews / Information Included in this NDA Review.

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Medical Review(s)	
Chemistry Review(s)	
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Statistical Review(s)	
Microbiology Review(s)	X
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:
NDA 19-863/S002

APPROVAL LETTER

NDA 19-863/S-002

MAY 28 1991

Serono Laboratories, Inc.
Attention: Ms. Martha J. Carter
Vice President, Regulatory Affairs
100 Longwater Circle
Norwell, MA 02061

Dear Ms. Carter:

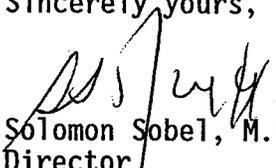
Reference is made to your supplemental new drug application dated March 6, 1991, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Geref (sermorelin acetate for injection).

The supplement provides for the procedures used for the environmental monitoring of airborne molds and yeasts of both air and surfaces in the

We have completed our review of this supplemental application and it is approved, effective on the date of this letter.

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

Sincerely yours,


Solomon Sobel, M.D.
Director

Division of Metabolism and
Endocrine Drug Products, HFD-510
Center for Drug Evaluation and Research

cc: NDA Arch.
HFD-510
HFD-160/DHussong/PCooney
HFD-80
HFD-510/CNiu/YYChiu
HFD-511/LBraithwaite/5.21.91/N19863AP.S02 /KO/FT/5/24/91
Concurrence: Short/5.21.91/Niu/Chiu/5.22.91

SUPPLEMENT APPROVAL

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:
19-863/S002

MICROBIOLOGY REVIEW

ORIGINAL

MAY 10 1991

CONSULTATIVE REVIEW TO HFD 510

MICROBIOLOGIST'S REVIEW OF SUPPLEMENT
DIVISION OF MEDICAL IMAGING, SURGICAL AND DENTAL DRUG PRODUCTS

May 2, 1991

NDA/Supplement Number: 19-863/S-002

Document Date: 6 March 1991

Amendments and Others: none

Name and Address of Applicant: Serono Laboratories
100 Longwater Circle
Norwell, MA 02061

Name of Drug: GEREFR[®] (sermorelin acetate for injection)

Supplement Provides For: Monitoring yeasts and molds in the

Pharmacological Category: growth hormone releasing factor

Dosage Form: lyophilized drug in _____

Related Documents: Microbiologist's Review's #1 (31 May 1989), #2 (14 February 1990) and #3 (16 August 1990)

Comments: The NDA was approved after accepting a commitment from the applicant to develop a monitoring program to detect and enumerate yeast and mold in the _____. The subject document (10 pages) provides validation data and methods from that study. Action Limits for environmental monitoring were provided in the 21 August 1989 submission and reviewed in Microbiologist's Review #2. The methods, data and conclusion are in keeping with the commitment and are appropriate for the environmental control program.

Conclusions and Recommendations: The supplement is recommended for approval.

David Hussong 5-2-91

David Hussong, Ph.D.

cc:
Orig. NDA 19-763/S-002
HFD 160/Consult File
HFD 510/CSD/LBraithwaite
drafted by: DHussong, 5/2/91
R/D init. by: PCooney, 5/2/91

7/2 5/2/91
Concur
J. Mori 5/20/91

MAY 10 1991

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ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date *MAR 12 1991*

NDA No. 19-863

SERONO LABORATORIES INC.
100 LONGWATER CIRCLE
ROSELAND, GA 30081 USA

Attention: Martha J. Carter

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: *CELEN* (cermorelin acetate for injection)

NDA Number: 19-863

Supplement Number: S-002

Date of Supplement: March 6, 1991

Date of Receipt: March 07, 1991

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation & Research HFD-510
Center for Drugs and Biologics, HFN-815
Attention: Document Control Room 12B-30
5600 Fishers Lane ~~XXXXX~~ 14E-03
Rockville, MD 20857

Best Possible Copy

Peter Smith
Peter Smith
Supervisory Consumer Safety Officer
Division of Anti-Infective Drug Products
Center for Drugs and Biologics

Division of Metabolism and
Endocrine Drug Products

cc:
NDA File
HFN-815 File
CSO File

