

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-863/S001

Trade Name: Geref

Generic Name: sermorelin acetate for injection

Sponsor: Serono Laboratories, Inc.

Approval Date: August 26, 1991

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RESEARCH**

APPLICATION NUMBER:
NDA 19-863/001

CONTENTS

Reviews / Information Included in this NDA Review.

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

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APPROVAL LETTER

NDA 19-863/S-001

AUG 26 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 January 14, 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 data to support the extension of the expiration date for Geref from 12 to 24 months when stored at 7°C.

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,

AS/23/91 *UB 8/22/91*
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
HFC-130/JAllen
HFD-80
HFD-500/LRipper
HFD-638
HFD-735
HFD-510/CNiu/YYChiu
HFD-511/LBraithwaite/ft/kso/8/22/91/N19863AP.S01
Concurrence: JShort/8/20/91/YYChiu/8/21/91 / CNiu / 8/21/91

SUPPLEMENT APPROVAL

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APPLICATION NUMBER:
NDA 19-863/S001

CHEMISTRY REVIEW(S)

3

ORIGINAL

AUG 12 1991

CHEMIST'S REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	19,863
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Serono Laboratories, Inc. 100 Longwater Circle Norwell, MA 02061		
5. NAME OF THE DRUG	6. NONPROPRIETARY NAME	8. AMENDMENTS/ REPORTS, DATE
Geref	Sermorelin acetate for injection	
7. SUPPLEMENT PROVIDES FOR:		RELATED IND/NDA/DMF
An extension of expiration date from twelve to twenty-four months.		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	
To stimulate production of growth hormone.	RX	
12. DOSAGE FORM	13. POTENCY	
Lyophilized Powder	50 mcg/vial	
14. CHEMICAL NAME AND STRUCTURE		
GRF(1-29)NH ₂ ; Chemical structure: see Chem. Rev. #1.		
15. COMMENTS		
The supplement provide stability data on separate lots of Geref stored at 7C for up to months.		
16. CONCLUSIONS AND RECOMMENDATIONS		
The submitted data support the shelf life of 24 months when Geref is stored at 7 C. Therefore, an extension of the expiration date for Geref from 12 to 24 months should be granted. Issue an approval letter.		
17. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Chien-Hua Niu, Ph.D.		8/7/91
DISTRIBUTION:	ORIGINAL JACKET	REVIEWER DIVISION FILE
R/D initialed by:	<i>J. Chiu 8/9/91</i>	
Disc Supplement: NDA19863.S01		

1 Page(s) Withheld

 ✓ § 552(b)(4) Trade Secret /
Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-19863
5001

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ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

ORIGINAL



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- GERMANY • ISRAEL • ITALY
- JAPAN • MEXICO •
- PORTUGAL • SINGAPORE •
- SPAIN • SWEDEN • SWITZERLAND • THE NETHERLANDS • UNITED KINGDOM
- USA • VENEZUELA

Noted
Reviews Completed
(See Chan. Rev. for S-001)



SERONO LABORATORIES, INC.
 100 LONGWATER CIRCLE
 NORWELL, MA 02061 - USA
 TEL. 1/617/9829000
 TLX. 6817456 SERONO UW

VICE PRESIDENT
 REGULATORY AFFAIRS

January 14, 1991

Solomon Sobel, M.D. *Chm 8/9/91*
 Director
 Division of Metabolism and Endocrine
 Drug Products, HFD-510
 Center for Drug Evaluation and Research
 Attn: Document Control Room, 14B-04
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

NDA NO. 19863 REF. NO. S/001
 NDA SUPPL FOR SCE

Noted
Alger
1/21

RE: NDA 19-863 Geref® (sermorelin acetate for injection)

Dear Dr. Sobel:

Reference is made to the above cited NDA and to its approval date of December 28, 1990. Pursuant to 21 CFR§314.70(b)(2)(ix), the purpose of this communication is to provide data to support the extension of expiration dating for this product from twelve (12) to twenty-four (24) months.

Enclosed are real time stability reports on separate lots of Geref® stored at 7° for up to months. The data show the product to be stable after 24 months of storage at 7°C.

Please do not hesitate to contact Dean F. Alger, Senior Regulatory Affairs Associate, or the undersigned with any questions you may have regarding this submission.

Sincerely,

Martha J. Carter
 Martha J. Carter

DFA/dlw
 Enclosure

REVIEWS COMPLETED

CSO ACTION:

LETTER N.A.I.

8/20/91

CSO INITIALS WB dlz/91 DATE