CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-680 / S-009

Trade Name: Norvir

Generic Name: (ritonavir)

Sponsor: Abbott Laboratories

Approval Date: May 21, 1998

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APPLICATION NUMBER:

20-680 / S-009

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 20-680/S-009

Ms. Rebecca A. Welch
Senior Regulatory Affairs Administrator
Abbott Laboratories
Dept. 491, AP6B-1
100 Abbott Park Road
Abbott Park, IL 60064-3500

Dear Ms. Welch:

Reference is made to your supplemental New Drug Application dated November 21, 1997, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR® (ritonavir) Capsules, 100 mg.

The User Fee goal date for this application is May 24, 1998.

This supplemental application provides for an [redacted] change for Ritonavir Capsules, 100 mg.

We have completed the 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.

If you have any questions, please contact Debra Gump, R.Ph., Regulatory Management Officer, at (301) 827-2335.

Sincerely yours,

Stephen P. Miller, Ph.D.
Chemistry Team Leader for
Division of Antiviral Drug Products (HFD-530)
DNDC-III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

APPROVED

Distribution:

NDA 20-680 Original	HFD-530/KLo	HFD-530/SMiller
HFD-530 Division File	HFD-830/CChen	District Office
HFD-530/DGump	HFD-530/KStruble	HFD-92/DDM-RMT

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APPLICATION NUMBER:

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CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-680

3. NAME AND ADDRESS OF APPLICANT *(City and State)*	4. AF NUMBER	
Abbott Laboratories Dept. 491, AP6B-1 100 Abbott Park Road Abbott Park, IL 60064-3500	5. SUPPLEMENT(S)	
	NUMBER(S)	DATE(S)
	SCP009 (CBE)	11/21/97

6. NAME OF DRUG	7. NONPROPRIETARY NAME
NORVIR	Ritonavir

8. SUPPLEMENT(S) PROVIDES FOR:	9. AMENDMENTS AND OTHER
An [redacted] hange for Ritonavir Capsules	*(Reports, etc)* DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Antiviral	|X| Rx | | OTC	

13. DOSAGE FORM	14. POTENCY(IES)
Capsules	100 mg

15. CHEMICAL NAME AND STRUCTURE	16. RECORDS AND REPORTS
10-Hydroxy-2-methyl-5-(1-methylethyl)-1-[2-(1-methylethyl)-4-thiazolyl]-3,6-dioxo-8,11-bis(phenylmethyl)-2,4,7,12-tetraazatridecan-13-oic acid, 5-thiazolylmethyl ester	*Current* | | Yes | | No *Reviewed* | | Yes | | No

17. COMMENTS

[redacted]

2. [redacted] - Description and mechanisms of the process were provided and found acceptabl (see Review Notes for details). No stability impact is expected since the [redacted] exposes produc to minimal heating [redacted]

3. Integrity of the [redacted] -- [redacted] analysis was performed. The data indicated that (i) the [redacted] provided an equivalent barrier to moisture when compared to the current h [redacted] met the USP requirements for a "tight closure" even after th [redacted] as broken. Data from in-process leak testing demonstrated that the [redacted] ere consistently formed.

4. Container Label -- Container label was revised to reflect the corresponding changes. A sample of container lab for Erythromycine Delayed-released Capsules, USP was provided as an example.

5. Stability Commitment -- Abbot has committed to place the first production batch on long-term stability testing using the approved production protocol in accordance with the 6/20/97 FDA letter.

18. CONCLUSIONS AND RECOMMENDATIONS

From a CMC standpoint, SCP009 is approved.

19.				**REVIEWER**		
NAME Ko-Yu Lo, Ph.D.		**SIGNATURE**		**DATE COMPLETED** 5/18/98		
20. CONCURRENCE: HFD-530/SMiller						
DISTRIBUTION	X	Original Jacket	X	Division File	X	KLo
	X	DGump	X	SMiller	X	CChen

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Chemistry Review Notes