CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-898 /S044

Trade Name: Pravachol Tablets

Generic Name: pravastatin sodium

Sponsor: Bristol-Myers Squibb

Approval Date: March 14, 2001

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APPLICATION NUMBER:

19-898 /S044

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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-898/S-044

Bristol-Myers Squibb
Attention: William J. Regan
Director, CMC, Regulatory Affairs
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Regan:

Please refer to your supplemental new drug application dated November 14, 2000, received November 16, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pravachol (pravastatin sodium) Tablets.

This supplemental new drug application provides for revisions to the currently approved stability protocol.

We have completed the review of this supplemental application, and it is approved.

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, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6418.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

/s/

Stephen Moore
3/14/01 01:40:50 PM

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APPLICATION NUMBER:

19-898 /S044

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. ORGANIZATION CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**2. NDA #** 19-898 Original NDA approved: 31-OCT-1991
3. NAME AND ADDRESS OF APPLICANT Bristol-Myers Squibb P.O. Box 5400 Princeton, NJ 08543 (Phone): 609-818-4732	**4. SUPPLEMENT** SCS-044 14-NOV-2001 (Rec. 16-NOV-2001)
	5. Name of the Drug PRAVACHOL™
	6. Nonproprietary Name Pravastatin sodium
7. SUPPLEMENT PROVIDES for revisions to the currently approved stability protocol.	**8. AMENDMENT** --

9. PHARMACOLOGICAL CATEGORY Lipid-lowering agent	**10. HOW DISPENSED** Oral	**11. RELATED** -N. A. -
12. DOSAGE FORM Tablet	**13. POTENCY** 10mg, 20mg and 40mg	

14. CHEMICAL NAME AND STRUCTURE

[1S-[1α(βS*,φS*)2α,6α,8β(R*),8α]]-1,2,6,7,8α-hexahydro-β,φ,6-trihydroxy-2-methyl-1-oxobutoxyl)-1-nephthaleneheptanoic acid, monosodium salt

15. COMMENTS See Next page.

16. CONCLUSIONS AND RECOMMENDATIONS The request to reduce the sampling as outlined in the approved stability protocol for [redacted] or a [redacted] meets CMC requirements. Issue Approval letter

17. REVIEWER NAME (AND SIGNATURE) **DATE**

COMPLETED 08-MAR-2001

Sharon Kelly, PhD

R/D INITIATED BY

filename: 19898#044 NDA

DISTRIBUTION: Original: sNDA 19-898 cc: HFD-510 Division File CSO Reviewer

AP

1 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 19-898 5044

/s/

Sharon Kelly
3/8/01 04:38:54 PM
CHEMIST

paper copy reviewed

Stephen Moore
3/8/01 05:02:26 PM
CHEMIST