CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-898 /S043

Trade Name: Pravachol Tablets

Generic Name: pravastatin sodium

Sponsor: Bristol-Myers Squibb

Approval Date: March 13, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898 /S043

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898 /S043

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-898/S-043

Bristol-Myers Squibb Company
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 September 7, 2000, received September 12, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pravachol (pravastatin sodium) Tablets.

We acknowledge receipt of your submission dated March 12, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate packaging site, , for 10 mg, 20 mg, and 40 mg tablets packaged in .

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
3/12/01 10:16:12 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898 /S043

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** SCM-043 07-SEPT-2000 (Rec. 12-SEPT-2000)
	5. Name of the Drug PRAVACHOL™
	6. Nonproprietary Name Pravastatin sodium
7. SUPPLEMENT PROVIDES for an alternate [redacted] packaging site in [redacted] for 10 mg, 20 mg, and 40 mg tablets packaged in [redacted]	**8. AMENDMENT** -- 12-MAR-2001

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 provide for one alternate [redacted] packaging site, a [redacted] meets CMC requirements. A Stability Commitment is included. Issue Approval letter

17. REVIEWER NAME (AND SIGNATURE) **DATE COMPLETED** 09-MAR-2001
Sharon Kelly, PhD
R/D INITIATED BY

filename: 19898#043 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
5043

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 19898/043
Priority: 1S
Org Code: 510
Stamp: 12-SEP-2000 Regulatory Due: 12-MAR-2001
Action Goal:
District Goal: 05-FEB-2001
Applicant: BRISTOL MYERS SQUIBB
RT 206 PROVINCE LINE RD
PRINCETON, NJ 085434000
Brand Name: PRAVACHOL TABLETS
Established Name:
Generic Name: PRAVASTATIN SODIUM
Dosage Form: TAB (TABLET)
Strength: 10, 20, 40 MG

FDA Contacts: S. KELLY (HFD-510) 301-827-6394 , Review Chemist
S. MOORE (HFD-510) 301-827-6430 , Team Leader

Overall Recommendation:

ACCEPTABLE on 09-MAR-2001 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: [redacted]
DMF No:
ADA No:

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 09-MAR-2001
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: [redacted]

/s/

Sharon Kelly
3/9/01 02:07:11 PM
CHEMIST

To be signed on March 12; paper copy reviewed

Stephen Moore
3/12/01 10:01:41 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S043

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DA 19-898/S-043

Food and Drug Administration
Rockville MD 20857

Bristol-Myers Squibb Company
P.O. Box 4000
Princeton, NJ 08543

SEP 19 2000

Attention: William J. Regan
Director CMC-Marketed Products
Regulatory Sciences and Outcomes Research

Dear Mr. Regan:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: PRAVACHOL® (pravastatin sodium) Tablets

NDA Number: 19-898

Supplement Number: S-043

Date of Supplement: September 7, 2000

Date of Receipt: September 12, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on November 11, 2000 in accordance with 21 CFR 314.101(a). All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 19-898/S-043
HFD-510/Div. Files
HFD-510/CSO/Simoneau

filename:

SUPPLEMENT ACKNOWLEDGEMENT

Bristol-Myers Squibb
Pharmaceutical Research Institute

P.O. Box 5400 Princeton, NJ 08543-5400
609 818-4732 Fax: 609 818-5832

William J. Regan
Director, CMC
Regulatory Science and Outcomes Research

Supplement -- Changes Being Effected in 30 Days

September 7, 2000

NDA 19-898
PRAVACHOL® (pravastatin sodium) Tablets

Dr. John Jenkins, M.D., Acting Director
Division of Metabolism and Endocrine Drug Products (HFD-150)
Center of Drug Evaluation and Research
Food and Drug Administration
Department of Health & Human Services
5600 Fishers Lane
Rockville, MD 20857

Attention: Document Control Room (14B-03)

Dear Dr. Jenkins:

Reference is made to our approved New Drug Application, NDA 19-898, for PRAVACHOL® (pravastatin sodium) Tablets, 10 mg, 20 mg, and 40 mg.

We are requesting to provide for two alternate packaging sites. The sites are:

The two above sites are

PRAVACHOL® (pravastatin sodium) 10 mg, 20 mg and 40 mg tablets will be packaged in at the alternate sites. All components of the package remain unchanged and have been previously approved.

Included in this supplement are two letters, one from each facility [redacted] stating compliance with cGMP and providing dates of the most recent FDA inspections. Also provided is Bristol-Myers Squibb's commitment to place product packaged at either facility into our marketed product stability program.

As recommended by the FDA Guidance for Industry titled, Changes to an Approved NDA or ANDA dated November 1999, we are submitting this as a *Changes Being Effected Supplement in 30 Days.* We cite section VI (C)(1)(c) of the guidance document, which provides for a "CBE" as the appropriate filing for this type of change. The effective date being 30 days after the date of this letter.

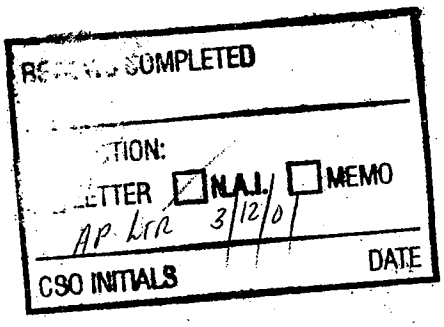
Bristol-Myers Squibb Company certifies that a field copy of this supplemental application has been provided to the North Brunswick office (120 North Center Drive, North Brunswick, NJ 08902) of the Food and Drug Administration. We further certify that the field copy is a true copy of this supplemental application.

Should you have any questions concerning this supplement, please contact me at (609) 818-4732.

Sincerely,

W.J. Regan

William J. Regan
Director
CMC - Marketed Products
Regulatory Sciences and Outcomes Research



DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0297
Expiration Date: 04-30-01

USER FEE COVER SHEET

See Instructions on Reverse Side Before Completing This Form

1. APPLICANT'S NAME AND ADDRESS

Randall D. Curtiss
Bristol-Myers Squibb Company
P.O. Box 5400
Princeton, NJ 08543

2. TELEPHONE NUMBER *(Include Area Code)*

(609) 818-5220

3. PRODUCT NAME
PRAVACHOL® (pravastatin sodium) Tablets

4. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL?
IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

IF RESPONSE IS 'YES', CHECK THE APPROPRIATE RESPONSE BELOW:

☐ THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION.

☐ THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO
(APPLICATION NO. CONTAINING THE DATA).

5. USER FEE I.D. NUMBER

6. LICENSE NUMBER / NDA NUMBER
NDA 19-898

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCLUSIONS**? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92
(Self Explanatory)

☐ A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE
(See Item 7, reverse side before checking box.)

☐ THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetics Act
(See Item 7, reverse side before checking box.)

☐ THE APPLICATION IS A PEDIATRIC SUPPLEMENT THAT QUALIFIES FOR THE EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food, Drug, and Cosmetic Act
(See Item 7, reverse side before checking box.)

☐ THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY
(Self Explanatory)

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ AN APPLICATION FOR A BIOLOGICAL PRODUCT FOR FURTHER MANUFACTURING USE ONLY

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGICAL PRODUCT LICENSED UNDER SECTION 351 OF THE PHS ACT

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?

☐ YES ☒ NO
(See reverse side if answered YES)

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0297)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Please **DO NOT RETURN** this form to this address.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
William J. Regan W. J. Regan	Director – CMC Marketed Products Regulatory Sciences and Outcomes Research	September 7, 2000

FORM FDA 3397 (5/98)

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