

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 19-898/S049

Trade Name: Pravacol Tablets

Generic Name: pravastatin sodium

Sponsor: Bristol Myers Squibb Company

Approval Date: January 14, 2002

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APPLICATION NUMBER:
NDA 19-898/S049

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APPLICATION NUMBER:
NDA 19-898/S049

APPROVAL LETTER

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/s/

Stephen Moore
1/14/02 12:05:35 PM

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APPLICATION NUMBER:
NDA 19-898/S049

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 4000 Princeton, NJ 08543-4000 (609)-252-4000	4. SUPPLEMENT SCM-049 19-JUL -2001 (Rec. 20-JUL - 2001)
	5. Name of the Drug PRAVACHOL™
	6. Nonproprietary Name Pravastatin sodium
7. SUPPLEMENT PROVIDES for three _____ sites for 10 mg, 20 mg and 40 mg tablets at _____	8. AMENDMENT --

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

14. CHEMICAL NAME AND STRUCTURE
 [1S-[1 α (β S*, ϕ S*)2 α ,6 α ,8 β (R*),8 α]]-1,2,6,7,8 α -hexahydro- β , ϕ ,6-trihydroxy-2-methyl-1-oxobutoxy)-1-nephthaleneheptanoic acid, monosodium salt

15. COMMENTS This supplement is submitted as a CBE-30. EES report attached. Overall recommendation is Acceptable.

CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information in NDA 19-898 SCM-049 is provided for the three _____ sites. All components of the _____ remain unchanged and are previously approved. A stability commitment for each facility is included. There are no deficiencies to be communicated to the sponsor. From the Chemistry viewpoint the application can be approved. Issue approval letter.

17. REVIEWER NAME (AND SIGNATURE) COMPLETED 07-JAN-2002 Sharon Kelly, PhD	DATE
--	-------------

filename: 19898#049 NDA

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

AP

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/s/

Sharon Kelly
1/7/02 04:39:33 PM
CHEMIST

Stephen Moore
1/7/02 04:43:22 PM
CHEMIST

**CENTER FOR DRUG EVALUATION AND
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APPLICATION NUMBER:
NDA 19-898/S049

ADMINISTRATIVE and CORRESPONDENCE
DOCUMENTS

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room, 14B-19
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call me at (301) 827-6411.

Sincerely,

{See appended electronic signature page}

Margaret Simoneau, R.Ph.
Regulatory Project Manager
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Margaret Simoneau
8/1/01 10:30:42 AM

Bristol-Myers Squibb Pharmaceutical Research Institute

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

ORIGINAL

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



NDA NO. 19898 REF. NO. 049
NDA SUPPL FOR SCM

Supplement – Changes Being Effectuated in 30 Days

July 19, 2001

NDA 19-898 PRAVACHOL® (pravastatin sodium) Tablets

Dr. John Jenkins, M.D., 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 three ~~_____~~ sites. The sites are:

~~_____~~

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

Handwritten notes:
7/23/01
CBE-20 "qualifies"
Please refer to
S. Kelly for determination
Mas
SK 7/24/01

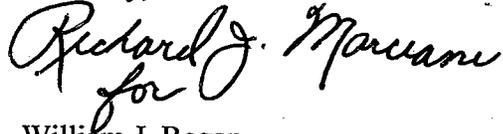
Included in this supplement are three letters, one from each facility stating compliance with cGMP and providing dates of the most recent FDA inspections. Also provided is Bristol-Myers Squibb's commitment to place product packaged at each facility into our marketed product stability program.

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,

A handwritten signature in cursive script that reads "Richard J. Mariani" with "for" written below it.

William J. Regan

Director

CMC - Marketed Products

Regulatory Sciences and Outcomes Research

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

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).

2. TELEPHONE NUMBER (Include Area Code)

(609) 818-5220

5. USER FEE I.D. NUMBER

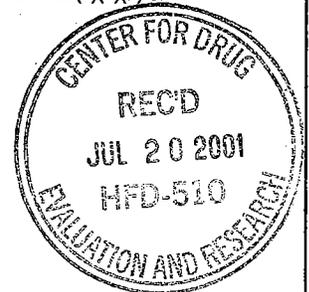
6. LICENSE NUMBER / NDA NUMBER
NDA 19-898

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)
- 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.)
- A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE
(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 COMMERCIALY
(Self Explanatory)

FOR BIOLOGICAL PRODUCTS ONLY

- WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION
- AN APPLICATION FOR A BIOLOGICAL PRODUCT FOR FURTHER MANUFACTURING USE ONLY
- A CRUDE ALLERGENIC EXTRACT PRODUCT
- 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

Richard Marciano for WJR
William J. Regan

TITLE

Director - CMC Marketed Products
Regulatory Sciences and Outcomes Research

DATE

July 19, 2001