CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-898/S041

Trade Name: Pravachol Tablets

Generic Name: pravastatin sodium

Sponsor: Bristol Myers Squibb

Approval Date: August 24, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S041

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S041

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-898/S-041

AUG 24 2000

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

Dear Mr. Regan:

Please refer to your supplemental new drug application dated February 29, 2000, received March 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pravachol (pravastatin sodium) Tablets.

We acknowledge receipt of your submissions dated March 28 and 30 and April 27, 2000.

This "Changes Being Effected in 30 days" supplemental new drug application provides for additional manufacture of 10 mg, 20 mg, and 40 mg tablets at the Mayaguez, Puerto Rico facility by [redacted] process and a change in the size [redacted] count bottle presentation.

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,

John Jenkins, M.D.
Acting Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDA 19-898
HFD-510/Div. Files
HFD-510/MAS
HFD-510/JWei/HAhn/SKelly/SMoore
HFD-095/DDMS-IMT
HFD-093/DDMS-IST
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/August 23, 2000
Initialed by: JWei8.23.00/HAhn8.23.00/SKelly8.23.00/SMoore8.23.00/EGalliers8.24.00
final: Mas8.24.00
filename: 19898.41

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S041

CHEMISTRY REVIEW(S)

APR 2 8 2000

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 (Phone): 609-252-4000	**4. SUPPLEMENT** SCF-041 29-FEB-2000 (Rec. 02-MAR-2000)
	5. Name of the Drug PRAVACHOL™
	6. Nonproprietary Name Pravastatin sodium
7. SUPPLEMENT PROVIDES for additional manufacture of 10mg, 20mg, and 40 mg tablets at the Mayaguez, Puerto Rico facility by [redacted] process and a change in the [redacted] count bottle presentation.	**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 Establishment Evaluation Request Summary Report attached.

16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided to support the change as indicated in item 7 above. From the Chemistry point of view, this supplement can be approved. Issue AP letter.

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

COMPLETED 28-APR-2000

Sharon Kelly, PhD

R/D INITIATED BY Sharon Kelly April 28, 2000

filename: 19898#041 NDA

DISTRIBUTION: Original: sNDA 19-898 SCF 041 cc: HFD-510 Division File CSO Reviewer

AP

Stephen Moore 4/28/2000

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 19898/041**
Priority: **1S**
Org Code: **510**
Stamp: **02-MAR-2000** Regulatory Due: **02-SEP-2000**
Action Goal:
District Goal: **29-JUL-2000**
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 30-MAR-2000 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: **2627673**
BRISTOL LABORATORIES INC DIV
FOREIGN TRADE ZONE #7 RD #114
MAYAGUEZ, PR 00680
DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **30-MAR-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**
Responsibilities: **FINISHED DOSAGE MANUFACTURER**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S041

CLINICAL PHARMACOLOGY AND BIOPHARMACEUTICS REVIEW(S)

MAR 24 2000

Clinical Pharmacology and Biopharmaceutics Review	
NDA:	**19-898**
Generic	**Pravastatin**
(Brand®)	**Pravachol®**
Sponsor	**Bristo-Myers Squibb**
Submission Date:	**02-29-2000**
Type of Submission:	**Supplement (SCF-041)**
Reviewer:	**Xiaoxiong (Jim) Wei, M.D., Ph.D.**

Synopsis

On February 29, 2000, Bristol-Myers Squibb (BMS) submitted this supplement to their approved NDA 19-898 for Pravachol® tablets for a change of manufacturing sites.

The sponsor is currently approved to manufacture, package, and control PRAVACHOL® reduced mass tablets made by [redacted] at Squibb Manufacturing, Inc., in Humacao, Puerto Rico. This supplement was submitted as *Changes Being Effected Supplement in 30 Days* to manufacture PRAVACHOL® reduced mass tablets made by [redacted] at Bristol-Myers Squibb Laboratories Company in Mayagüez, Puerto Rico.

In support of this application and based on SUPAC-IR guidance, section IV (C)(2), the sponsor provided the dissolution profiles comparing [redacted] of each potency of PRAVACHOL® tablets manufactured at the proposed and approved sites. The dissolution results show that PRAVACHOL® 10 mg and 40 mg reduced mass tablets manufactured by [redacted] in Mayagüez, Puerto Rico is comparable to the corresponding drug product manufactured at the Humacao, Puerto Rico facility, but not for 20 mg tablets because the SUPAC similarity factors (f2) are 50, 47, and 59 for the 10 mg, 20 mg and 40 mg strengths, respectively.

Are the dissolution profiles similar to each other (reference versus test manufacture sites)?

A [redacted] tablet dissolution profile for [redacted] of PRAVACHOL® 10 mg, 20 mg and 40 mg reduced mass tablets manufactured in Mayagüez, Puerto Rico (test batch) was compared with the dissolution profile for a corresponding [redacted] tablets manufactured in Humacao, Puerto Rico (reference batch). Both the reference and test batches were tested for dissolution profiles in water using USP apparatus 2 (paddles) at 50 rpm. Aliquots were removed at [redacted] and [redacted] minute intervals.

The sponsor provided f2 values of 52, 50 and 59 for 10-mg, 20-mg and 40-mg tablets, respectively. The reviewer re-calculated f_2 values and they are different. The re-calculated f2 values for the 10 mg, 20 mg and 40 mg strengths are 50, 47 and 59, respectively.

The calculated f2 values by the reviewer indicate that the dissolution profiles for the 10 mg and 40 mg are similar between the two sites but not for the 20 mg tablets.

COMMENT TO BE SENT TO THE SPONSOR:

The calculated f2 values by the reviewer indicate that the dissolution profiles for the 10 mg and 40 mg are similar between the two sites but not for 20 mg tablets (f2=47). The difference between the reviewer and the sponsor is that the sponsor used [redacted] dissolution of both products. Based on our guidance *(Dissolution Testing of Immediate Release Solid Oral Dosage Forms)*, only one measurement should be considered after 85% dissolution of both products.

RECOMMENDATIONS

The Office of Clinical Pharmacology and Biopharmaceutics/Division of Pharmaceutical Evaluation II (OCPB/DPE-2) has reviewed a supplement to NDA 19-898 for Pravachol® submitted on 02-29-2000. The re-calculated f2 values indicate that the change of manufacture sites is acceptable for the 10 mg and 40 mg tablets, but not for 20 mg tablets. However, it may not be necessary that a bioequivalence study be conducted for the 20-mg tablets for the following reason:

> A drug product can be considered rapid dissolving when not less than 85% of the label amount of the drug substance dissolves within 30 minutes in three different media and a bioequivalence study may be waived based on our draft guidance (*Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate Release Solid Oral Dosage Forms Containing Certain Active Moieties/Active Ingredients Based on a Biopharmaceutics Classification System*).

Therefore, an additional dissolution study for 20-mg tablets in three different media within 30 minutes is recommended (see our draft guidance on the internet for details). This recommendation and the comment above should be sent to the sponsor as appropriate.

Xiaoxiong (Jim) Wei, M.D., Ph.D.

Division of Pharmaceutical Evaluation II
Office of Clinical Pharmacology and Biopharmaceutics

~~RD~~ FT initialed by Hae-Young Ahn, Ph.D., Team Leader 3/24/00

CC: NDA 19-898 (orig., 1 copy), HFD-510(Simoneau), HFD-850(Lesko), HFD-870(Huang, Ahn, Wei), CDR.

Code: AE

Attachment: Study Summary of Dissolution Profiles

6 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Clin Pharm/Bio- 19-898 S041

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-898/S041 `

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR - 6 2000

NDA 19-898/S-041

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

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

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-041
Date of Supplement:	February 29, 2000
Date of Receipt:	March 2, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on May 1, 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-041
HFD-510/Div. Files
HFD-510/CSO/Simoneau

filename: C:\WPWIN61\WPDOCS\19898.WPDC:\DATA\WPFILES\19898.WPD

SUPPLEMENT ACKNOWLEDGEMENT

ORIGINAL

NDA SUPP AMEND
S-041 BC

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

April 27, 2000

Amendment to NDA 19-898/S-041
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 and specifically to supplemental application S-041, which provides to manufacture the reduced mass formulation of the drug product via a ——— process at our Mayagüez, Puerto Rico facility.

Additional reference is made to the Agency's fax (attached) of March 30, 2000 requesting the ———presentation in the ——— placed on stability. Bristol-Myers Squibb commits to the FDA's comments as noted in the referenced fax.

Bristol-Myers Squibb Company certifies that a field copy of this correspondence 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 letter.

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

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

Sincerely,

Richard J. Moreani

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

NDA SUPP AMEND
SCF-041-BC

ORIGINAL

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

March 30, 2000

Amendment to NDA 19-898/S-041
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 and specifically to supplemental application S-041, which provides to manufacture the reduced mass formulation of the drug product via a [redacted] process at our Mayagüez, Puerto Rico facility.

Additional reference is made to our correspondence of March 28, 2000 where we officially requested to FDA an extension of the implementation date of S-041 to April 10, 2000 in order to have time to provide the requested additional dissolution data for the 20-mg strength. We are now providing dissolution results for the 20-mg strength showing that not less than 85% of the label amount of pravastatin sodium dissolves within 30 minutes in the following media: [redacted]

Bristol-Myers Squibb Company certifies that a field copy of this correspondence 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 letter.

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

REVIEWS COMPLETED
APlla 8-24-00
CSO ACTION:
☒ LETTER ☐ N.A.I. ☐ MEMO
Mlas 8/25/00
CSO INITIALS fwd DATE
to Spruce

NDA SUPP AMEND
SCF-041-BM
BC

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

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

March 28, 2000

NDA 19-898/S-041
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)

SK 4/7/00 Noted

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, and specifically to supplemental application S-041 which provides for manufacture of the reduced mass formulation via [redacted] at our Mayaguez, PR facility.

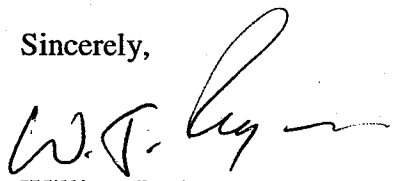
Additional reference is made to the Agency's March 27, 2000 fax (attached), and to the March 28, 2000 phone conversation between Margaret Simoneau (FDA), Stephen Moore (FDA), et al (FDA), and William Regan (Bristol-Myers Squibb) in which it was agreed to extend the effective date of S-041 in order to provide the Agency with the requested additional dissolution data. Our expectation is to have the requested data shortly. At this time we are extending the implementation date to April 10, 2000. Further, as requested we are committing to place into our routine marketed life stability program the [redacted] count presentation in the new container.

We also confirm that both [redacted] manufacturing processes will continued to be used in NDA 19-898.

Bristol-Myers Squibb Company certifies that a field copy of this correspondence 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 letter.

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

Sincerely,



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

ORIGINAL

Bristol-Myers Squibb
Pharmaceutical Research Institute

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

NDA NO. 19898 REF. NO. 041
NDA SUPPL FOR SCE

William J. Regan
Director, CMC
North American Regulatory Affairs

Supplement -- Changes Being Effected in 30 Days

February 29, 2000

Noted 5/23/00

NDA 19-898
PRAVACHOL® (pravastatin sodium) Tablets

John Jenkins, M.D
Acting Director, Division of Metabolism and Endocrine Drug Products (HFD-510)
Center of Drug Evaluation and Research
Food and Drug Administration
Department of Health & Human Services
5600 Fishers Lane
Rockville, MD 20857

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. Additional references are made to the following:

- S-008 (approved 2/9/94), which provided for a reduced mass formulation of the tablets, and

- S-025 (approved 4/9/99), which allowed the reduced mass formulation to be manufactured by [redacted] at our Humacao, PR facility.

We now request to provide for manufacture of the reduced mass formulation via [redacted] at our Mayaguez, PR facility. The Mayaguez facility is currently approved to manufacture the reduced mass formulation via [redacted] (S-008). Mayaguez is also an approved packaging and control site.

REVIEWS COMPLETED
ACTION:
LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

Further, we are providing for a change in the [redacted] container used for the [redacted] count presentation. Although reportable in the annual report, we are including it in this submission as a less burdensome notification of the change as allowed in 21 CFR 314.70.

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.* 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.

A detailed summary of this supplement may be found in the Introduction and Summary Section. In addition, a Table of Contents describing the components of this submission follows this letter.

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

Sincerely,

Donald M. Kessler

for 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	February 29, 2000

FORM FDA 3397 (5/98)

Created by Electronic Document Services/USDHHS: (301) 443-2454 EF