CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-261/S011

Trade Name: Lescol Capsules

Generic Name: fluvastatin sodium

Sponsor: Novartis Pharmaceuticals Corporation

Approval Date: October 8, 1998

Indications: .

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

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Microbiology Review(s)	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-261/S-011

OCT 8 1998

Novartis Pharmaceuticals Corporation
Attention: Donna Kapples
CMC, Drug Regulatory Affairs
59 Route 10
East Hanover, New Jersey 07936-1080

Dear Ms. Kapples:

Please refer to your supplemental new drug application dated October 1, 1996, received October 4, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lescol (fluvastatin sodium) Capsules.

We acknowledge receipt of your submissions dated October 21,1997, and April 8 and October 5 (fax), 1998. Your submission of April 8, 1998 constituted a full response to our April 3, 1997, action letter.

This supplemental new drug application provides for replacement of the current [redacted] method for determination of sodium ion in the drug substance with the USP <191> ID test for sodium.

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, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

Stephen K. Moore 10/8/98

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

cc:
Archival NDA 20-261
HFD-510/Div. Files
HFD-510/M. Simoneau
HFD-95/DDMS
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/October 7, 1998
Initialed by:WBerlin 10.7.98/SMoore10.7.98/EGalliers10.7.98
final:Mas10.8.98
filename: 20261.11

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

APPROVABLE LETTER

NDA 20-261/S-011

APR 3 1997

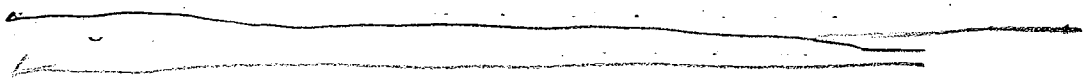
Sandoz Pharmaceutical Corporation
Attention: Mr. Robert J. Clark
59 Route 10
East Hanover, NJ 07936-1080

Dear Mr. Clark:

Please refer to your supplemental new drug application dated October 1, 1996, received October 4, 1996, submitted under section 505(d) of the Federal Food, Drug, and Cosmetic Act for Lescol® (fluvastin sodium) Capsules.

The User Fee goal date for this application is April 4, 1997.

We have completed our review and find the information presented is inadequate, and the supplemental application is not approvable under section 505(d) of the Act and 21 CFR 314.125(b). The supplemental application is deficient for the following reason:



Please contact the Agency to discuss criteria for an acceptable reduction in the frequency of testing.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw the supplemental application. Any amendment should respond to the deficiency listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until the deficiency has been addressed.

If you have any questions, please contact Ms. Margaret Simoneau, R.Ph., Consumer Safety Officer, at 301-443-3510.

Sincerely yours,

Stephen K. Moore 4/2/97

Stephen K. Moore, Ph.D.
Chemistry Team Leader I, DNDC II
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

NDA Original 20-261
HFD-510
HFD-510/WBerlin/SMoore
HFD-511/MSimoneau
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted: Jweber/4/2/97/N20261.SNA 4/3/97

Concurrence: Egalliers 4/2/WBerlin 4/2/SMoore 4/2/97
Final: Jweber/4/2/97

NOT APPROVABLE (NA)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

CHEMISTRY REVIEW(S)

ORIGINAL

OCT 6 1998

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER
	DMEDP II, HFD-510	20-261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Sandoz Pharmaceuticals Corporation 50 Route 10 East Hanover, NJ 07936-1080		SCS-011 10-1-1996
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Lescol Capsules	Fluvastatin Sodium	10-21-1997 4-8-1998 10-5-1998

8. SUPPLEMENT PROVIDES FOR

Replacement of the current [redacted] method for determination of sodium ion in the drug substance with the USP <191> ID test for sodium.

9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
antihypercholestremic	RX	
12. DOSAGE FORM	13. POTENCY	
Capsules	20, 40, 80 mg	

14. CHEMICAL NAME AND STRUCTURE

See Chemistry Review #1

COMMENTS

The original S-011 requested a reduction in the frequency of testing [redacted], as well as testing for sodium ion by an [redacted] method. A not-approvable letter was issued in response to the original application (letter dated 4-4-97), and the sponsor filed an intent to amend S-011 with a letter dated 4-8-97. Subsequently, two amendments were submitted [redacted]

Therefore, the sponsor provided the last amendment (dated 10-5-98) withdrawing the proposal to [redacted] Lastly, the sponsor has proposed to change the current regulatory method for the determination of sodium ion in the drug substance. The sponsor will delete the current [redacted] method and will replace it with the USP <191> method for identification of sodium in the drug-substance tests and specifications list. This change is acceptable.

16. CONCLUSION AND RECOMMENDATION

The change from [redacted] to the USP <191> for the determination of sodium ion in the drug substance tests and specifications is acceptable. The sponsor should be advised that the revised drug-substance tests and specifications list should be updated in the next annual report. Issue an approval letter.

17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN		10-5-98

DISTRIBUTION: ORIGINAL JACKET CSO REVIEWER DIVISION FILE

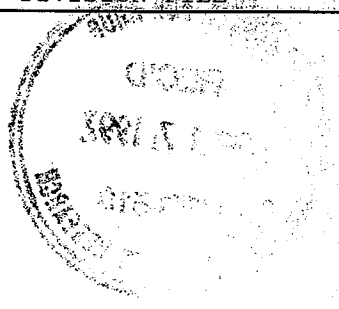
AP

Stephen K. Moore
10/6/98

ORIGINAL

CHEMISTS REVIEW	1. ORGANIZATION	2. NDA NUMBER APR 1 1997
	DMEDP II, HFD-510	20-261
3. NAME AND ADDRESS OF APPLICANT		4. SUPPLEMENT NUMBER, DATE
Sandoz Pharmaceuticals Corporation 50 Route 10 East Hanover, NJ 07936-1080		SCS-011 10-1-96
5. PROPRIETARY NAME	6. NAME OF THE DRUG	7. AMENDMENTS, REPORT, DATE
Lescol Capsules	Fluvastatin Sodium	
8. SUPPLEMENT PROVIDES FOR		
[redacted]		
9. PHARMACOLOGICAL CATEGORY	10. HOW DISPENSED	11. RELATED IND, NDA, DMF
antihypercholestremic	RX	
12. DOSAGE FORM	13. POTENCY	
Capsules	20, 40, 80 mg	
14. CHEMICAL NAME AND STRUCTURE		
See Chemistry Review #1		
15. COMMENTS		
[redacted]		
16. CONCLUSION AND RECOMMENDATION		
Issue a not-approvable letter. The following should be communicated in the not-approvable letter: [redacted]		
17. NAME	18. REVIEWERS SIGNATURE	19. DATE COMPLETED
WILLIAM K. BERLIN	[signature]	4-1-97
DISTRIBUTION: ORIGINAL JACKET	CSO REVIEWER	DIVISION FILE

Stephen K. Moore
4/1/97



1 Page(s) Withheld

1 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-20-26 / SD11

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

STATISTICAL REVIEW(S)

3.1

ORIGINAL

STATISTICAL REVIEW AND EVALUATION
(Chemistry, Manufacturing and Controls)

(Review of Sponsor's Statistical Sampling Size Calculations for the [redacted])

Date: AUG 3 1998

NDA#: 20-261

Applicant: Novartis Pharmaceuticals Corporation

Name of Drug: LESCOL (fluvastatin sodium) Capsules

Documents Reviewed: Amendment to Pending Supplemental New Drug Application S-011, dated October 21, 1997

Supplemental New Drug Application - Chemistry, dated October 1, 1996

Amendment to Pending Supplemental New Drug Application S-011, dated April 8, 1998

[redacted]

Reviewing Chemist: William Berlin, Ph.D., ODE II, HFD-510

Statistical Reviewer: Karl K. Lin, Ph.D., DOB II/OEB, HFD-715

Introduction

This report contains the reviewer's evaluation of the sponsor's statistical sampling plan for the [redacted]

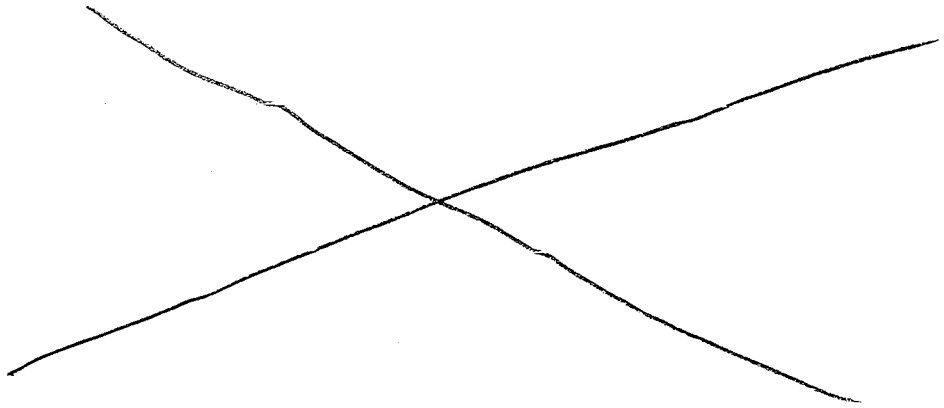
2 Page(s) Withheld

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

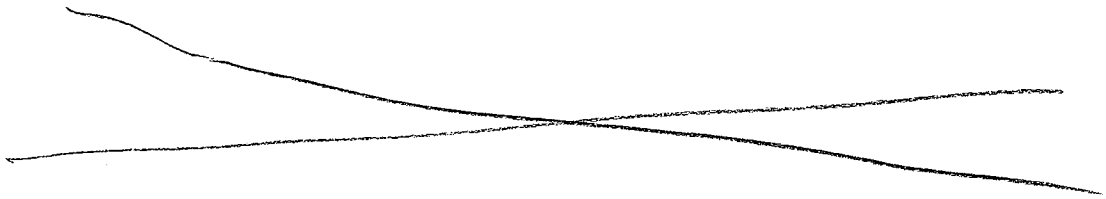
_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Statistical- 20-261
5041
Stat Review #1



Summary



Karl K. Lin, Ph.D.
Expert Mathematical Statistician

Concur:
S. Edward Nevius, Ph.D.
Director
Division of Biometrics II

cc: NDA 20-261
HFD-510/WBerlin, Division File
HFD-715/ENevius, Klin, Division File, Chron

SCS-OH BC 10.21.97

SCS 011 BC 361

ORIGINAL

STATISTICAL REVIEW AND EVALUATION
(Chemistry, Manufacturing and Controls)

Date: MAR 16 1998

NDA#:	20-261
Applicant:	Novartis Pharmaceuticals Corporation
Name of Drug:	LESCOL (fluvastatin sodium) Capsules
Documents Reviewed:	Amendment to Pending Supplemental New Drug Application S-011, dated October 21, 1997 Supplemental New Drug Application - Chemistry, dated October 1, 1996
Reviewing Chemist:	William Berlin, Ph.D., ODE II, HFD-510
Statistical Reviewer:	Karl K. Lin, Ph.D., DOB II/OEB, HFD-715

Introduction

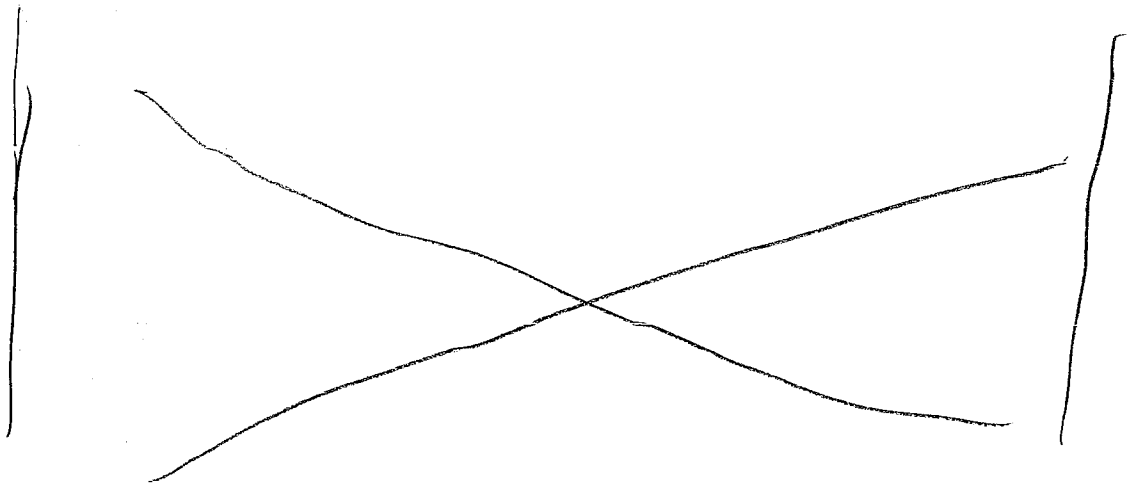
In the chemistry supplemental new drug application dated October 1, 1996, based on the vast amount of historical data accumulated, the sponsor proposed to [redacted] sodium ion [redacted] Dr. William Berlin of HFD-510, reviewing chemist of this NDA, made a request that the sponsor submit a statistical sampling plan for the proposed [redacted] Responding to the request, the sponsor submitted a proposed statistical sampling plan in the amendment to the above chemistry supplement on October 21, 1997. Dr. Berlin requested that the Division of Biometrics II perform a statistical review and evaluation on the appropriateness of the proposed statistical sampling plan.

Sponsor's Proposed Statistical Sampling Plan

Based on the consistent historical data o[redacted]batches of fluvastatin sodium manufactured, the sponsor proposed the following statistical sampling plan for the [redacted] sodium ion [redacted] The sponsor modified its original plan of [redacted] October 21, 1997 amendment to the October 1,

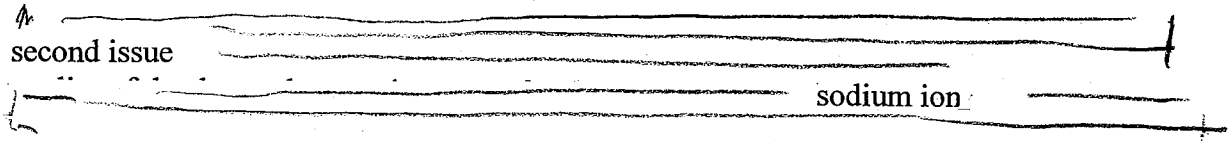
1996 supplement.

The Sponsor's submitted statistical sampling plan includes the following components:

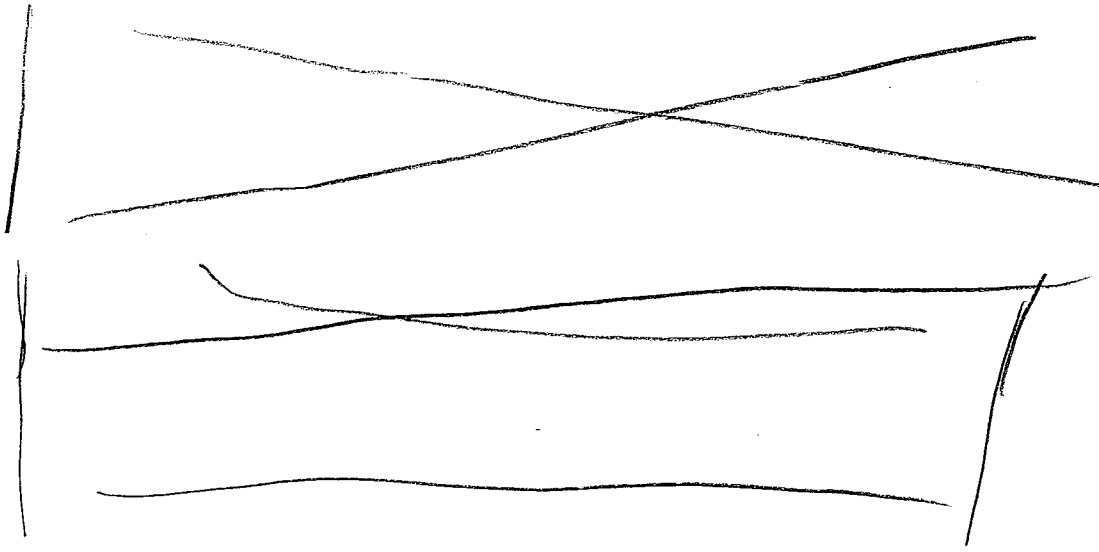


Reviewer's Analysis and Comments

(1). There are two statistical issues in the chemistry supplement and amendment. The first issue



(2). One of the Agency's main concern in reviewing the sponsor's request for



2 Page(s) Withheld

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

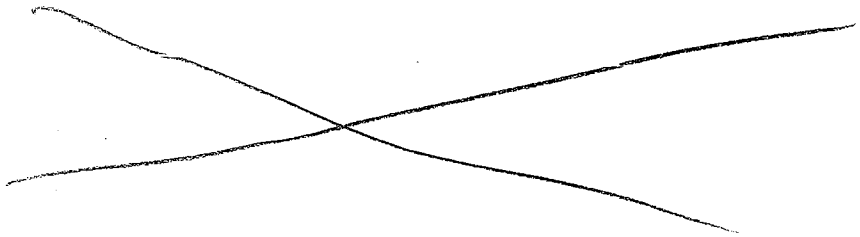
_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Statistical- 20-261
S011
Stat Review
1

Second, the sponsor proposed [redacted]

(5)



References

1. Bowker, A. H. and G. J. Liberman (1972), Engineering Statistics, Second Edition, Prentice-Hall, Englewood Cliff, New Jersey.

2. Fisher, L.D., and G.V. Belle (1993), Biostatistics: A Methodology for the Health Sciences, John Wiley, New York.

3. Snedecor, G.W., and W.G. Cochran (1967), Statistical Methods, Sixth Edition, The Iowa State University Press, Ames, Iowa.

Karl K. Lin

Karl K. Lin, Ph.D.
Expert Mathematical Statistician

Concur: 3-16-98

S. Edward Nevius, Ph.D.
Director
Division of Biometrics II

cc: NDA 20-261
HFD-510/WBerlin, Division File
HFD-715/ENevius, Klin, Division File, Chron

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-261/S011

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

ORIGINAL

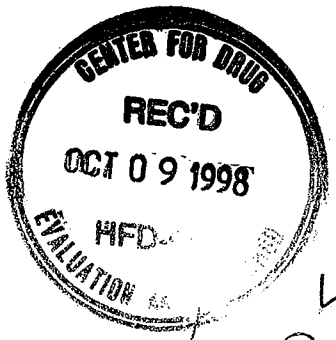
Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 973 781 7500
Fax 973 781 6325

NOVARTIS

October 5, 1998

SUPPL NEW CORRESP
S-011 SNC



S-011

NDA 20-261/S-011
Lescol® Capsules
(fluvastatin sodium)

Amendment to Pending Supplemental New Drug Application

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

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(b), Novartis Pharmaceuticals Corporation herewith submits an amendment to supplement, S-011, for Lescol (fluvastatin sodium) Capsules. Novartis is [redacted] fluvastatin sodium. Also, Novartis is [redacted] but commits to replace the [redacted] test for the determination of sodium ion with USP<191> flame test, the ID test for sodium.

Supplement S-011 (originally submitted on October 1, 1996) provided for the [redacted] drug substance, fluvastatin sodium. On April 4, 1997, Novartis received a not approvable letter for S-011. A notification of intent to amend S-011 was submitted on April 8, 1997. Subsequent amendments were submitted on October 21, 1997 and April 8, 1998 to provide a statistical plan for the [redacted] fluvastatin sodium.

At this time, Novartis is [redacted] fluvastatin sodium [redacted] The issues involved with this proposal (submitted in amendments to S-011, dated October 21, 1997 and April 8, 1998) have not yet been resolved. It is in Novartis' best business interest to [redacted] current situation where fluvastatin sodium is [redacted]

for Sharon Hertz
RW Steggerda
11/17/98

Novartis is [redacted] fluvastatin sodium. However, Novartis does commit to replace the [redacted] test for the determination of sodium ion with USP<191> flame test, the ID test for sodium. The switch to the USP ID test for sodium was the suggestion of Dr. William Berlin, reviewing chemist, Division of Metabolic and Endocrine Drug Products in his effort to provide workload relief, in lieu of approving a [redacted] fluvastatin sodium.

Should you have any comments or questions regarding this submission or any other Chemistry, Manufacturing and Controls issue, please contact me directly at (973) 781-6929. If there are any general or clinical related issues, please contact Jerry Klimek, DRA Therapeutic Area at (973) 781-8145.

Sincerely,

Donna Kapples

Donna Kapples

Chemistry, Manufacturing and Controls

Drug Regulatory Affairs

cc: Ms. Regina Brown, New Jersey District Office, North Brunswick Resident Post

REVIEWS COMPLETED
AP ltr 10-8-98
CSO ACTION:
☑ LETTER ☐ N.A.I. ☐ MEMO
Mar 11-18-98
CSO INITIALS DATE

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

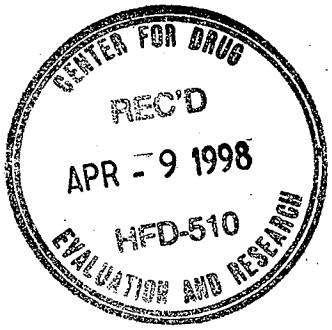
Tel 973 781 7500
Fax 973 781 6325

NDA SUPPL AMENDMENT

NOVARTIS

ORIGINAL

April 8, 1998



NDA 20-261/S-011
Lescol® Capsules
(fluvastatin sodium)

Amendment to Pending Supplemental New Drug Application

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

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(B), Novartis Pharmaceuticals Corporation herewith submits an amendment to supplement, S-011, for Lescol (fluvastatin sodium) Capsules. This amendment is in response to FDA comments provided to Novartis in a FDA fax dated 26-Mar-98 (provided for convenience in Attachment #1).

The intent of the supplement was to r fluvastatin sodium. The amendment to the supplement, submitted on 21-Oct-97, provided a sampling plan FDA statistician, Mr. Karl Lin, provided comments to Dr. William Berlin (reviewing chemist, Division of Metabolic and Endocrine Drug Products) suggesting that Novartis perform a sample size calculation.

This amendment provides the results as determined by the sample size calculation for

Since both methods yield similar sample sizes, of fluvastatin sodium

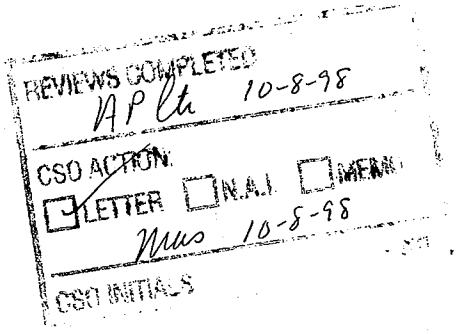
If you have any questions or comments, please contact me at (973) 781-6929.

Sincerely,

Donna Kapples

Donna Kapples
Chemistry, Manufacturing and Controls
Drug Regulatory Affairs

cc: Ms. Regina Brown, New Jersey District Office, North Brunswick Resident Post



FOOD AND DRUG ADMINISTRATION
DATE : 3-26-98
DIVISION OF METABOLIC AND
ENDOCRINE DRUG PRODUCTS, HFD-510
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

ORIGINAL

TO:

Name: Donna Kapples, Novatris Pharmaceuticals

Fax No.: (973) 781-6325

Phone No.: (973) 503-6929

Location: East Hanover, NJ

Pages: (including cover) 2

FROM:

Name: William K. Berlin, Ph.D.

Fax No.: (301) 827-0878

Phone No.: (301) 827-6370

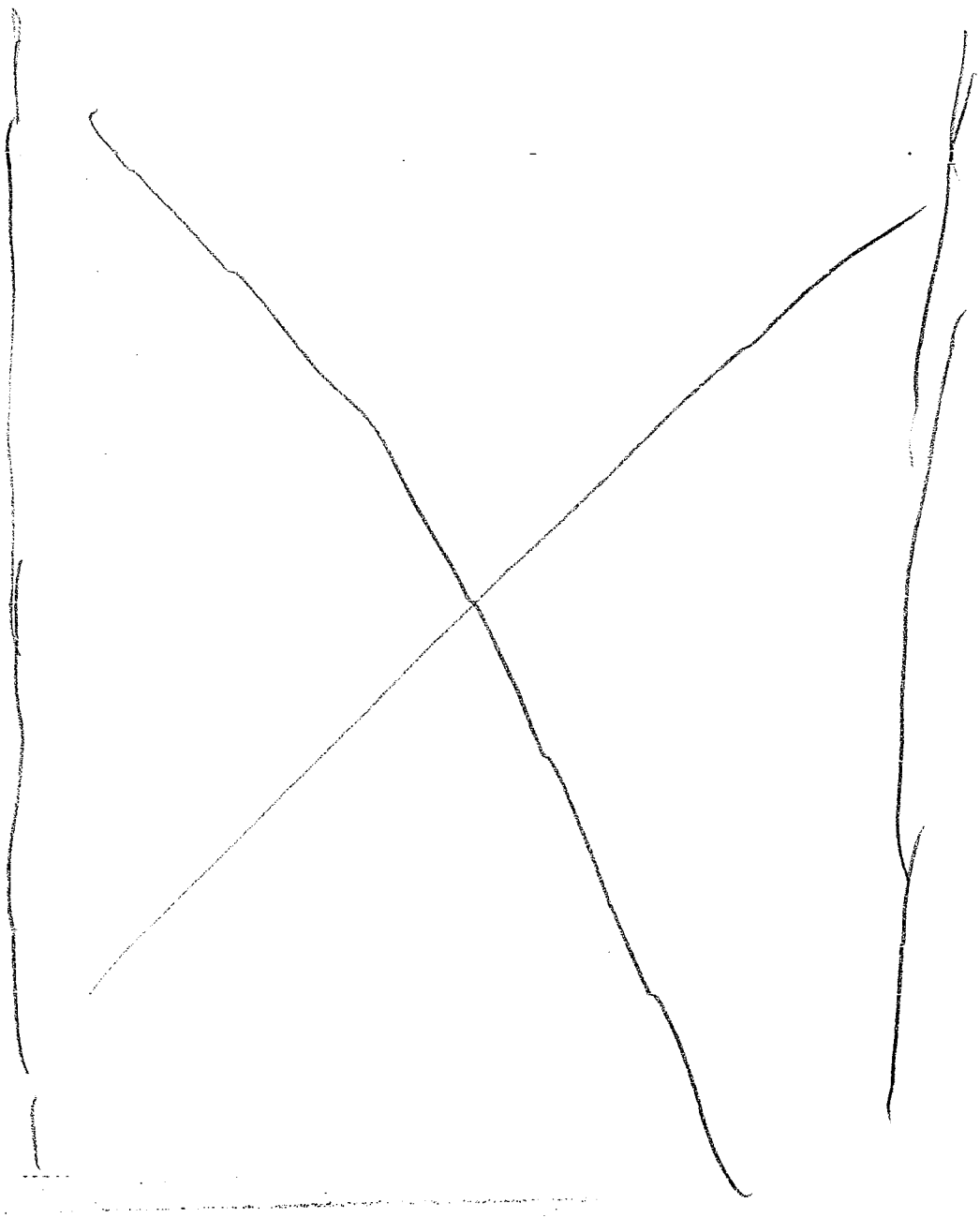
Location: FDA/CDER

Comments:

Excerpts from the Statistical review to assist the sponsor in addressing questions raised by the Statistical Reviewer.

Cleared for FAXING By: Stephen K. Moore 3/26/98

CC: NDA 20261/S-011
Div File
Berlin B



References

1. Bowker, A. H. and G. J. Liberman (1972), Engineering Statistics, Second Edition, Prentice-Hall, Englewood Cliff, New Jersey.

2. Fisher, L.D., and G.V. Belle (1993), Biostatistics: A Methodology for the Health Sciences, John Wiley, New York.

3. Snedecor, G.W., and W.G. Cochran (1967), Statistical Methods, Sixth Edition, The Iowa State University Press, Ames, Iowa.

NDA SUPPL AMENDMENT
SCS-011 SC

ORIGINAL

NOVARTIS

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

October 21, 1997

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

NDA No. 20-261/S-011

LESCOL® (fluvastatin sodium) Capsules

AMENDMENT to PENDING SUPPLEMENTAL NEW DRUG APPLICATION

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(B), Novartis Pharmaceuticals Corporation herewith submits an amendment to supplement, S-011, for Lescol (fluvastatin sodium) Capsules. Supplement S-011 (submitted on October 1, 1996, [redacted]

[redacted]

S-011. A notification of intent to amend S-011 was submitted on April 8, 1997.

Supplement S-011 originally proposed the [redacted]

[redacted]

In previous discussions held between Dr. William Berlin (reviewing chemist, Division of Metabolic and Endocrine Drug Products) and Mr. Robert Clark (from the former Sandoz Pharmaceuticals Corporation), Dr. Berlin recommended the submission of a statistical sampling plan [redacted] At this time, we are providing a statistical sampling plan that does achieve this goal (Attachment #2).

This plan provides [redacted]

[redacted]

developed by a Novartis consultant to ensure [redacted]

[redacted]

Please also find attached a summary

Novartis is confident that product quality will not be affected by the fluvastatin sodium. In further support of our claim, the following should be emphasized:

-
- Fluvastatin Sodium
-
- Historical data demonstrates

A certified copy of this NDA amendment to supplement S-011 is being provided to our local office in compliance with the preapproval inspection requirements.

If you have any questions or comments, please contact me at (973) 503-6929.

Sincerely,

Donna Kapples

Donna Kapples
Chemistry, Manufacturing and Controls
Drug Regulatory Affairs

REVIEWS COMPLETED
AP 10-8-98
CSO ACTION:
☑ LETTER ☐ N.A.I. ☐ MEMO
Mas 10-9-98
CSO INITIALS DATE

/cjw
Attachments
Submitted in duplicate

cc: Ms. Regina Brown, New Jersey District Office, North Brunswick Resident Post

10/8/98

SNC-011

Novartis Pharmaceuticals Corporation
Drug Regulatory Affairs
59 Route 10
East Hanover, NJ 07936-1080

Tel 201 503 7500
Fax 201 503 6325

NOVARTIS

April 8, 1997

ORIGINAL

Soloman Sobel, MD
Director
Division of Metabolism and
Endocrine Drug Products/HFD-510
Office of Drug Evaluation II
Attn: Document Control Room 14B-04
Center for Drug Evaluation and
Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-261/S-011
LESCOL® (fluvastatin sodium) Capsules

Notification of Intent to Amend a Supplemental New Drug Application

7/8/97

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
APR 10 1997
HFD-510

Dear Dr. Sobel:

Please refer to the above cited supplemental new drug application for Lescol® (fluvastatin sodium) Capsules. This supplement (submitted on October 1, 1996) provides for [redacted] drug substance, fluvastatin sodium.

Please also refer to your letter of April 4, 1997 which finds this application not approvable. We note that Novartis is required to respond to your letter within ten days of its issuance.

This letter serves as written confirmation, in accordance with 21 CFR 314.120 (a), that Novartis Pharmaceuticals Corporation intends to amend S-011. It is understood that this confirmation of intent to amend also constitutes agreement to extension of the review period under 21 CFR 314.60.

If you have any questions or comments, please contact me at (201) 503-7005.

Sincerely,

Robert J. Clark
Associate Director,
Drug Regulatory Affairs

REVIEWS COMPLETED
CSO ACTION
☐ LETTER ☒ N.A.I. ☐ MEMO
8/25/97
DATE
CSO INITIALS

Submitted in duplicate

noted
EKB
8/25/97

8/22/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date OCT 15 1996

NDA No. 20-261

SANDOZ PHARMACEUTICALS CORPORATION
59 Route 10
East Hanover, New Jersey 07936-1080

Attention: Robert J. Clark, Senior Manager, Regulatory Manufacturing & Control

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: LESCOL (fluvastatin sodium) Capsules

NDA Number: 20-261

Supplement Number: S-011

Date of Supplement: October 1, 1996

Date of Receipt: October 4, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on DEC - 3 1996 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
Attention: Document Control Room
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office Drug Evaluation II
Center for Drug Evaluation and Research

NDA SUPPLEMENT ORIGINAL

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080

SANDOZ

NDA NO. 20261 SUPPL. NO. 011

NDA SUPPL. FOR SCS

DRUG REGISTRATION & REGULATORY AFFAIRS

TEL. 201 503 7500
FAX 201 503 6325

October 1, 1996

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products/HFD-510
Office of Drug Evaluation II
Attn: Document Control Room 14B-04
Center for Drug Evaluation and
Research
5600 Fishers Lane
Rockville, Maryland 20857

NDA No. 20-261
LESCOL® (fluvastatin sodium) Capsules

SUPPLEMENTAL NEW DRUG APPLICATION

CHEMISTRY

Dear Dr. Sobel:

In accordance with 21 CFR §314.70(b)(2), Sandoz Pharmaceuticals Corporation herewith submits a supplemental new drug application for Lescol® (fluvastatin sodium) Capsules. This supplement provides

Sandoz would like to reduce

; see the introduction for a complete justification of the

Please see the table of contents for a list of all supportive documentation. A certified copy of this NDA supplement is being provided to our local district office in compliance with the preapproval inspection requirements.

If you have additional questions or comments, please contact me at (201) 503-7005.

REVIEWS COMPLETED

CSO ACTION:
☒ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS 4/2/97 DATE

Sincerely

Robert J. Clark
Senior Manager, Regulatory
Manufacturing and Controls

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT 04 1996
HFD-510

Attachments
Submitted in duplicate
cc: Mr. Matthew Lewis, Newark District Office