CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21008

CHEMISTRY REVIEW(S)

Wdai

NOV 19 1998

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-008

DATE REVIEWED: November 19, 1998

CHEMISTRY REVIEW #: 3

REVIEWER: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	5/29/98	6/2/98	6/2/98
Amendment	11/10/98	11/12/98	11/17/98

NAME & ADDRESS OF APPLICATION:

Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936
Tel: (973)781-7661
Fax: (973)781-6325

DRUG PRODUCT NAME:

Proprietary:	Sandostatin LAR Depot
Established:	Octreotide acetate for injectable suspension
Code Name:	None
Chem. Type/Ther. Class:	1 P

DOSAGE FORM: Microsphere Depot

STRENGTHS: 10 mg/vial, 20 mg/vial, and 30 mg/vial

CONCLUSION AND RECOMMENDATION:
The sponsor's response to chemistry deficiencies is satisfactory. Moreover, cGMP inspections for facilities manufacturing the drug substance, the diluent, and the drug product have been completed and found to be acceptable by the Office of Compliance. Because there are no more pending CMC issues, this application can be approved from chemistry viewpoint. However, the sponsor should be reminded that the test methods are under validation. If any problems or questions arise, their cooperation in finalizing the procedure is required.

/S/

APPEARS THIS WAY
ON ORIGINAL

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/JWeber/SMoore
HFD-820/JGibbs
R/D init. by:
File Name: NDA21008N01R
AP

APPEARS THIS WAY
ON ORIGINAL

/S/ 11/19/98

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-008

DATE REVIEWED: November 4, 1998

CHEMISTRY REVIEW #: 2

REVIEWER: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	5/29/98	6/2/98	6/2/98
Amendment	10/21/98	10/22/98	10/27/98
Amendment	10/22/98	10/23/98	10/27/98
Amendment	10/28/98	10/29/98	10/29/98

NAME & ADDRESS OF APPLICATION:

Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936
Tel: (973)781-7661
Fax: (973)781-6325

DRUG PRODUCT NAME:

Proprietary:	Sandostatin LAR Depot
Established:	Octreotide acetate for injectable suspension
Code Name:	None
Chem. Type/Ther. Class:	1 P

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of acromegaly, malignant carcinoid tumor, and VIPoma

DOSAGE FORM: Microsphere Depot

STRENGTHS: 10 mg/vial, 20 mg/vial, and 30 mg/vial

CONCLUSION AND RECOMMENDATION:
The sponsor has properly answered most of the chemistry deficiencies in their 10/22/98 amendment. The application remains approvable. The additional information
of deliverable dose as well as other minor issues delineated.

/S/

Chien-Hua Niu, Ph.D.
Review Chemist

APPEARS THIS WAY
ON ORIGINAL

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/JWeber/SMoore
HFD-820/JGibbs
R/D init. by:
File Name: NDA21008N01A
AE

/S/
11/5/98

APPEARS THIS WAY
ON ORIGINAL

Weber

OCT 8 1998

DIVISION OF METABOLIC AND ENDOCRINE DRUG PRODUCTS

Review of Chemistry, Manuacturing and Controls

NDA #: 21-008

DATE REVIEWED: October 1, 1998

CHEMISTRY REVIEW #: 1

REVIEWER: Chien-Hua Niu, Ph.D.

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	5/29/98	6/2/98	6/2/98

NAME & ADDRESS OF APPLICATION:

Novartis Pharmaceuticals Corp.
59 Route 10
East Hanover, NJ 07936
Tel: (973)781-7661
Fax: (973)781-6325

DRUG PRODUCT NAME:

Proprietary:	Sandostatin LAR Depot
Established:	Octreotide acetate for injectable suspension
Code Name:	None
Chem. Type/Ther. Class:	1 P

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of acromegaly, malignant carcinoid tumor, and VIPoma

DOSAGE FORM: Microsphere Depot

STRENGTHS: 10 mg/vial, 20 mg/vial, and 30 mg/vial

ROUTE OF ADMINISTRATION: Deep IM Depot Injection

CONCLUSION AND RECOMMENDATION:
Sufficient information on chemistry, manufacturing and controls of the drug product has been submitted for the NDA. Therefore, the drug product is approvable from chemistry viewpoint provided that (1) cGMP inspection of the facility used for manufacturing the drug product is found to be acceptable.

APPEARS THIS WAY
ON ORIGINAL

/S/

Chien-Hua Niu, Ph.D.
Review Chemist

cc: Org. NDA
HFD-510/Division File
HFD-510/CHNiu
HFD-510/JWeber/SMoore
HFD-820/JGibbs
R/D init. by:
File Name: NDA21008N001

APPEARS THIS WAY
ON ORIGINAL

/S/
10/8/98