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RESEARCH**

APPLICATION NUMBER:

21-688

CHEMISTRY REVIEW(S)

NDA 21-688

SENSIPAR (cinacalcet hydrochloride) 30, 60, 90 mg Tablets

CHEMISTRY DIVISION DIRECTOR REVIEW

Applicant: Amgen, Inc.
Address: One Amgen Center Dr.
Thousand Oaks, CA

Representative:
Pamela Danagher, Manager Regulatory Affairs
(805) 447-1000

Indication: Treatment of secondary hyperparathyroidism in pts with chronic kidney disease not undergoing dialysis and for treatment of primary hyperparathyroidism when parathyroidectomy is not a treatment option

Presentations: 30, 60, 90 mg tablets in HDPE bottles of 30. _____
_____ Physician sample HDPE bottles of 7
count are also qualified. Bottles contain filler and a desiccant.

EER Status: Acceptable 26-FEB-2004

Consults: DMETS – SENSIPAR is acceptable 08-NOV-2003
Statistics – none
Biopharm – dissolution tests, acceptance criteria OK
EA – no consult - waiver requested - granted

The SENSIPAR NDA was submitted 05-SEP-2003. CMC IR letters were issued 13-NOV-2003, 23-dec-2003, AND 26-jan-2004 (EMail) and was responded to in the amendments dated 03-DEC-2003 and 12-JAN-2004, and 03-FEB-2004. The NDA was designated Priority.

The drug substance is manufactured by:

Structural characterization of the drug substance, and chirality determination was satisfactory. _____
_____ was agreed at a pre-NDA

[REDACTED]

Conclusion

Drug substance information is acceptable.

The drug product is a film coated immediate release tablet in strengths of 30, 60, 90 mg.

[REDACTED]

[REDACTED]

Submitted stability data support the proposed 24 month expiry. The stability protocol and commitment are acceptable. Labeling is acceptable.

All associated DMFs are acceptable.

Overall Conclusion

From a CMC perspective the application an approval action is recommended.

Eric P Duffy, PhD
Director, DNDC II/ONDC

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/s/

Eric Duffy
3/8/04 11:51:05 AM
CHEMIST

NDA 21-688

SENSIPAR™ (cinacalcet hydrochloride) Tablets

Amgen Inc.

Shulin Ding, Ph.D.

Division of Metabolic and Endocrine Drug Products

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