

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

213224Orig1s000

STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION CLINICAL STUDIES

NDA/BLA #: NDA 213,224
Supplement #: Original NDA, 505b(2) relying on NDA 19,667
Drug Name: Octreotide Acetate Injection, 2.5 mg/mL, 2.8 mL, Pen Injector
Indication(s): For the treatment of acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, and profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP) secreting tumors
Applicant: Sun Pharmaceutical Industries Limited
Date(s): PDUFA goal date: January 28, 2020
Review Priority: Standard
Biometrics Division: Division II
Statistical Reviewer: Yoonhee Kim, PhD
Concurring Reviewers: Feng Li, PhD, Acting Team Leader
Medical Division: Division of Metabolism and Endocrinology Products
Clinical Team: Geanina Roman-Popoveniuc, MD
Marina Zemskova, MD, Team Leader
Project Manager: Meghna Jairath

Keywords: 505b(2), Octreotide

MEMORANDUM

This NDA is submitted under section 505(b)(2) relying on SANDOSTATIN® (octreotide acetate, NDA 19,667), approved on October 21, 1988. The Applicant developed a new drug-device combination product, Octreotide Acetate Injection, 2.5 mg/ML, 2.8 mL, Pen Injector. This drug is a new formulation of octreotide acetate, in a solution with 2.5 times the concentration of the highest available concentration of SANDOSTATIN® Injection. The proposed labeling in this submission does not contain Section 14.

No new datasets for statistical review were submitted. Other submitted files including clinical overview, bioanalytical report, and human factor study report for this submission are in the location: <\\CDSesub1\evsprod\NDA213224\0001>

No new clinical data were submitted for this NDA submission. No formal statistical evaluation was needed. There are no statistical issues to refrain from approval of this submission.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

YOONHEE KIM
10/17/2019 01:23:01 PM

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10/17/2019 01:31:46 PM