CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-688

MEDICAL REVIEW

CLINICAL REVIEW

Division of Metabolic and Endocrine Drug Products (HFD-510)

Application #:	21-688	**Application Type:**	NDA
Sponsor:	Amgen	**Proprietary Name:**	Sensipar
Pharmaceutical Category:	Calcimimetic	**Route of Administration:**	Oral
Indications:	Treatment of Secondary Hyperparathyroidism and Parathyroid Carcinoma	**Dosage:**	30 – 180 mg
Reviewers:	Theresa Kehoe, MD Patricia Beaston, MD, PhD Eric Colman, MD	**Date Review Completed:**	2/20/04

Chemistry Reviewer: Sheldon Markofsky, Ph.D.
Pharmacology Reviewer: Gemma Kuijpers, Ph.D.
Biopharmaceutics Reviewer: Johnny Lau, Ph.D.
Statistical Reviewer: Joy Mele, M.S.

REVIEW SUMMARY: See Executive Summary

OUTSTANDING ISSUE: See Executive Summary

RECOMMENDED REGULATORY ACTION: N drive location:

New clinical studies _____ **Clinical Hold** _____ **Study May Proceed**

NDA, Efficacy/Label supplement: _____ **Approvable** _____ **Not Approvable**
_____ **Approve**

SIGNATURES:

Medical Reviewers: Theresa Kehoe, M.D. **Date:** _____
Patricia Beaston, M.D. Ph.D.

Medical Team Leader: Eric Colman **Date:** _____

Table of Contents

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.