

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**21-688**

**MEDICAL REVIEW**

# CLINICAL REVIEW

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

<b>Application #:</b> 21-688	<b>Application Type:</b> NDA
<b>Sponsor:</b> Amgen	<b>Proprietary Name:</b> Sensipar
<b>Pharmaceutical Category:</b> Calcimimetic	<b>Route of Administration:</b> Oral
<b>Indications:</b> Treatment of Secondary Hyperparathyroidism and Parathyroid Carcinoma	<b>Dosage:</b> 30 – 180 mg
<b>Reviewers:</b> Theresa Kehoe, MD Patricia Beaston, MD, PhD Eric Colman, MD	<b>Date Review Completed:</b> 2/20/04
<b>Chemistry Reviewer:</b> Sheldon Markofsky, Ph.D. <b>Pharmacology Reviewer:</b> Gemma Kuijpers, Ph.D. <b>Biopharmaceutics Reviewer:</b> Johnny Lau, Ph.D. <b>Statistical Reviewer:</b> Joy Mele, M.S.	
<b>REVIEW SUMMARY:</b> See Executive Summary	
<b>OUTSTANDING ISSUE:</b> See Executive Summary	
<b>RECOMMENDED REGULATORY ACTION:</b>	N drive location:
New clinical studies _____	Clinical Hold _____
_____	Study May Proceed _____
NDA, Efficacy/Label supplement: _____	Approvable _____
_____	Not Approvable _____
_____	Approve _____
<b>SIGNATURES:</b>	
<b>Medical Reviewers:</b> Theresa Kehoe, M.D. Patricia Beaston, M.D. Ph.D.	<b>Date:</b> _____
<b>Medical Team Leader:</b> Eric Colman	<b>Date:</b> _____

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