CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-688

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmacoepidemiology and Statistical Science
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA/Serial Number:	21-688
Drug Name:	SENSIPAR (cinacalcet HCl)
Indication(s):	_____ treatment of secondary hyperparathyroidism in patients with Chronic Kidney Disease, receiving or not receiving dialysis. Treatment of hypercalcemia in patients with parathyroid carcinoma, or in patients with primary hyperparathyroidism for whom parathyroidectomy is not a treatment option.
Applicant:	Amgen
Date(s):	Submitted 9/5/03. PDUFA due date 3/8/04
Review Priority:	Priority
Biometrics Division:	Division of Biometrics 2 (HFD-715)
Statistical Reviewer:	Joy Mele, M.S.
Concurring Reviewers:	Todd Sahlroot, Ph.D. (Team Leader) Ed Nevius, Ph.D. (Division Director)
Medical Division:	Division of Metabolic and Endocrine Drug Products (HFD-510)
Clinical Team:	Theresa Kehoe, M.D (Medical Reviewer) Patricia Beaston, M.D. (Medical Reviewer) Eric Colman, M.D. (Team Leader) David Orloff, M.D. (Division Director)
Project Manager:	Randy Hedin

Keywords: NDA review, Clinical studies, Safety analyses

1. EXECUTIVE SUMMARY OF STATISTICAL FINDINGS

1.1 Conclusions and Recommendations

The applicant's proposed indications for cinacalcet (sensipar) are the following:

- Treatment of hypercalcemia in patients with primary hyperparathyroidism or with parathyroid carcinoma
- Treatment of secondary hyperparathyroidism
- Control of parathyroid hormone (PTH), serum calcium x phosphorus, phosphorus and calcium levels in patients with chronic kidney disease receiving or not receiving dialysis

With regard to primary hyperparathyroidism, this reviewer has the following comments and conclusions based on this statistical review:

- [redacted]
- [redacted]
- [redacted] No assessment of safety can be made just based on 990120 since clearly patients with serious ADE's in 980125 would not continue into 990120.
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

With regard to secondary hyperparathyroidism in patients with ESRD and receiving dialysis, this reviewer has the following comments and conclusions based on this statistical review:

- Three Phase 2 studies showed that doses above 50 mg per day are usually needed to significantly impact PTH particularly in patients with baseline PTH above about 525.
- In the three large Phase 3 studies (172, 183 and 188), about 39% had mild HPT

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