

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-597

PHARMACOLOGY REVIEW

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: October 24, 2003

FROM: Supervisory Pharmacologist
Division of Gastrointestinal and Coagulation Drug Products, HFD-180

SUBJECT: NDA 21,597 (Serostim) Amendment Dated August 27, 2003- Revised Labeling.

TO: NDA 21,957

In amendment dated August 27, 2003, the sponsor included revised labeling. In the revised labeling, the following statement was added under ' _____

_____” Presumably this statement is based on a publication by Ulshen et al, Gastroenterology 104: 973-980, 1993. This publication deals with transgenic mice overexpressing bovine growth hormone. It does not, however, involve experimentation with administration of serostim. Pharmacology review (February 13, 1996) of NDA 20,604 (HFD-510) for serostim does not indicate any direct experimentation in animals to determine the effect of serostim on the intestines. Under the circumstances, it appears that the above statement is not well founded.

It is our recommendation that the inclusion of the statement in the labeling be denied.

Jasti B. Choudary, B.V. Sc., Ph.D. Date
Supervisory Pharmacologist, HFD-180

cc:
NDA
HFD-180
HFD-181/CSO
HFD-180/Dr. Choudary

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/s/

Jasti Choudary
10/24/03 04:22:03 PM
PHARMACOLOGIST