MEMORANDUM

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

DATE: May 29, 2003

FROM: Alice Kacuba, R.N., MSN, RAC, Regulatory Project Manager,
for Robert L. Justice, M.D., M.S., Director
Division of Gastrointestinal and Coagulation Drug Products,
HFD-180

SUBJECT: Briefing Document for the June 25, 2003 Meeting of the Gastrointestinal Drugs Advisory Committee on Serostim? [somatotropin (rDNA origin) for injection] for "the treatment of short bowel syndrome"

MEETING TIME: 8:30AM – 5:00PM

MEETING LOCATION: Marriott Washingtonian Center, The Ballrooms,
9751 Washingtonian Blvd., Gaithersburg, MD

Please find enclosed the following items:
Attachment 1: Medical Officer Review
Attachment 2: Statistical Review

The attached package contains background information prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. The FDA background package often includes initial reviews and/or preliminary conclusions and recommendations written by individual FDA reviewers. These conclusions and recommendations do not necessarily represent the final position of the individual reviewer, nor do they necessarily represent the final position of the FDA. The FDA will not take a final action on the application until input from the advisory committee has been considered and all reviews have been finalized.

In order to aid your review of the documents provided by the FDA as well as Serono Inc., we would like to focus on the following topics:

- The number of patients studied;
- The number of studies conducted;
- The influence of diet on the outcomes;
- The primary endpoint (total IPN volume) selected in support of this indication.

The final questions will be given to you prior to the actual meeting.
We look forward to your participation and seeing you on June 25, 2003.