



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 15, 2002

Thomas J. Bucknum
Biogen, Inc.
Fourteen Cambridge Center
Cambridge, MA 02142

Dear Mr. Bucknum:

Your petition to the Food and Drug Administration requesting that the labeling of Serono's REBIF and any promotional or advertising materials for such product are neither false nor misleading, was received by this office on 04/15/02. It was assigned docket number 02P-0154/CP 1 and it was filed on 04/15/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,


Gloria Ortega
Dockets Management Branch

02P-0154

ACK 1