DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our STN: BL 101063/5012

AUG 1 2002

Taryn Rogalski-Salter, Ph.D.
Merck and Company, Incorporated
Sumneytown Pike
P.O. Box 4 UN-B121
West Point, PA 19486-0004

Dear Dr. Rogalski-Salter:

Your request to supplement your biologics license application for Asparaginase (ELSPAR®) to add a Geriatric Use subsection in the Precautions section of the package insert has been approved.

We acknowledge your commitment of July 22, 2002 to revise the package insert to contain a new subsection under "ADVERSE REACTIONS" entitled "Immunogenicity". This new subsection will be based on existing ELSPAR® clinical data, such as published literature reports and relevant study reports. As such, this subsection will provide information to the extent that is available from the literature review regarding the immunogenicity of ELSPAR®. The literature search (to include contacting cooperative groups and investigators) for identification of available data will be completed by February 28, 2003 and a supplemental application containing the proposed labeling revisions and supporting documentation will be submitted by July 31, 2003.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

This information will be included in your biologics license application file.

Sincerely yours,

Karen D. Weiss, M.D.
Director
Division of Clinical Trials
Design and Analysis
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research

Enclosure: Final draft labeling