



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

Our STN: BL 103628\5115

FEB - 2 2007

Biogen Idec, Inc.  
Attention: Nadine D. Cohen, Ph.D.  
Senior Vice President, Regulatory Affairs  
14 Cambridge Center  
Cambridge, MA 02142

Dear Dr. Cohen:

Your request to supplement your biologics license application for Interferon Beta-1a (Avonex®) to add an additional intramuscular needle size to the package insert as an alternative needle has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and the submitted labeling. Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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).

Please refer to <http://www.fda.gov/cder/biologics/default.htm> for important information regarding therapeutic biological products, including the addresses for submissions.

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

Sincerely,

Russell Katz, MD  
Director  
Division of Neurology Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure