

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125290

PHARMACOLOGY REVIEW(S)

MEMORANDUM

**DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration**

**Division of Neurology Products (HFD-120)
Center for Drug Evaluation and Research**

Date: June 3, 2009

From: Barbara J. Wilcox, Ph.D.

Through: Lois M. Freed, Ph.D.

Subject: BLA 125290

No new nonclinical data were submitted with this BLA. Labeling recommendations have been conveyed to the medical team. Approval and labeling recommendations are based on previously reviewed nonclinical studies that were conducted using Betaseron. At the time of this approval, Extavia and Betaseron are the same product.