

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
125290

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

Clinical Pharmacology/Biopharmaceutics Review

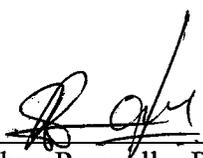
PRODUCT (Generic Name):	Interferon beta-1b
BLA:	125290
SUBMISSION DATE	05/06/2008
PRODUCT (Brand Name):	Extavia
DOSAGE FORM:	Subcutaneous Injection
DOSAGE STRENGTHS:	0.25 mg
INDICATION:	Relapsing Multiple Sclerosis
SPONSOR:	Novartis
REVIEWER:	Jagan Mohan Parepally, Ph.D.
TEAM LEADER:	Veneeta Tandon, Ph.D.
OCP DIVISION:	DCP 1
OND DIVISION:	HFD 120

EXECUTIVE SUMMARY

Extavia is a subcutaneous injection drug product for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. Extavia does not differ from Betaseron. It contains the same drug product and has identical indication. No new data was presented in this application. There were no new clinical pharmacology studies to review in this BLA.

Recommendation

The PLR Labeling information proposed by the Sponsor is acceptable without any changes.



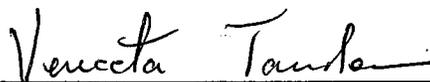
Jagan Mohan Parepally, Ph.D.

Reviewer

Division of Clinical Pharmacology 1

06/08/2009

Date



Veneeta Tandon, Ph.D.

Team Leader

Division of Clinical Pharmacology 1

06/08/2009

Date

cc: HFD-120 BLA# 125290
HFD-860 Mehul Mehta, Ramana Uppoor, Veneeta Tandon, Jagan Mohan Parepally,