CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-641/S-008

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021641/S-002/S-003/S-004/S-005/S-007/S-008/S-010

SUPPLEMENT APPROVAL

Teva Pharmaceutical Industries LTD.
c/o Teva Neuroscience, Inc.
Attention: Dennis Ahern, Director, U.S. Regulatory Affairs
425 Privet Road
P.O. Box 1005
Horsham, PA 19044-8005

Dear Mr. Ahern:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for for AZILECT® (rasagiline mesylate) Tablets:

Application	Submitted on:	Received on:	Amended on:	Proposes: :
NDA 021641/S-002	February 1, 2007	February 2, 2007	May 9, 2008	Labeling related to reports of compulsive behavior with Parkinson's disease medications.
NDA 021641/S-003	May 11, 2007	May 14, 2007	None	Labeling change in warning section.
NDA 021641/S-004	June 1, 2007	June 4, 2007	None	Labeling changes regarding melanoma in Parkinson's disease.
NDA 021641/S-005	October 26, 2007	October 29, 2007	None	Labeling change in warning and precautions sections.
NDA 021641/S-007	May 19, 2008	May 19, 2008	None	Labeling change resulting from the Phase IV commitment dose proportionality study.
NDA 021641/S-008	February 6, 2009	February 9, 2009	July 16, 2009; November 24, 2009; December 3, 2009	Labeling revisions regarding selectivity of AZILECT® for MAO-B and additional related changes.
NDA 021641/S-010	April 10, 2009	April 13, 2009	None	CBE Labeling changes in the adverse reactions section relative to postmarketing regarding cases of serotonin syndrome and elevated blood pressure.

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA** NDA 021641/S-002/S-003/S-004/S-005/S-007/S-008/S-010"

HIGHLIGHTS SECTION OF LABELING

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Stacy Metz, PharmD, Regulatory Project Manager, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

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

Enclosure
Content of Labeling