



Our STN: BLA 125075/130

MAR 13 2009

Genentech, Inc.
Attention: Sarah Baker
Manager, Regulatory Affairs
Department of Regulatory Affairs
1 DNA Way MS#241B
South San Francisco, CA 94080-4990

Dear Ms. Baker:

Please refer to your supplemental biologics license application (BLA) dated January 27, 2009, received January 28, 2009, for RAPTIVA[®] (efalizumab).

This prior approval supplement provides for the addition of safety information regarding Progressive Multifocal Leukoencephalopathy (PML) to the BOXED WARNING, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS sections of the package insert and the conversion of the Patient Package Insert to a Medication Guide in accordance with 21 CFR Part 208.

We have completed our review of this supplemental application, as amended, and it is approved, effective on the date of this letter, for use of RAPTIVA[®] as recommended in the enclosed agreed-upon labeling text.

Please note that:

- this Medication Guide must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling [21 CFR 201.57(c)(18)] or 21 CFR 201.80(f)(2)];
- you are responsible for ensuring that this Medication Guide is available for distribution to every patient who is dispensed a prescription for RAPTIVA[®] [21 CFR 208.24];
- the final printed Medication Guide distributed to patients must conform to all conditions described in 21 CFR 208.20, including a minimum of 10 point text; and

- you are responsible for ensuring that the label of each container or package includes a prominent and conspicuous instruction to authorized dispensers to provide a Medication Guide to each patient to whom the drug is dispensed, and states how the Medication Guide is provided [21 CFR 208.24(d)].

The approved Medication Guide will be one element of the proposed Risk Evaluation and Mitigation Strategy (REMS) you submitted in supplement STN BLA 125075/ (b), dated November 13, 2008. We will provide comments on the other elements of your proposed REMS in a separate letter to STN BLA 125075/(b)

CONTENT OF LABELING

Within 14 days of the date of this letter, submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "Product Correspondence – Final SPL for approved STN BLA 125075/130." In addition, within 14 days of the date of this letter, amend any pending supplement(s) for this BLA with content of labeling in SPL format to include the changes approved in this supplement.

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

We request that you issue a "Dear Health Care Professional" letter to inform health care professionals about the safety-related changes to the package insert and the addition of a Medication Guide as approved in this supplement. Please submit an electronic copy of the letter to both this BLA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

PROMOTIONAL MATERIALS

You may request advisory comments on proposed advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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 www.fda.gov/cder/ddmac.

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80). You should submit postmarketing adverse experience reports to the following address:

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA-3486 to the following address:

Division of Compliance Risk Management and Surveillance
(HFD-330) Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Biological product deviations sent by courier or overnight mail should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Division of Compliance Risk Management and Surveillance
(HFD-330) Montrose Metro 2
11919 Rockville Pike
Rockville, MD 20852

If you have any questions, call Catherine Carr, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

A handwritten signature in cursive script that reads "Susan J. Walker for".

Susan J. Walker, M.D., F.A.A.D.
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (Package insert, Medication Guide, and Carton/Container Labels)