



NDA 20-080/S-038

SUPPLEMENT APPROVAL

Glaxo Group Limited
d/b/a GlaxoSmithKline
Attention: Christopher J. Stotka, PharmD
Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr Stotka:

Please refer to your Supplemental New Drug Application (sNDA) dated June 30, 2006 received June 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imitrex (sumatriptan succinate) Injection.

We also acknowledge receipt of your amendments dated October 31, 2006 and April 11, 2007.

This “Changes Being Effected” supplemental new drug application was submitted in response to an Agency Letter dated April 28, 2006 and provides information about Selective Serotonin Reuptake Inhibitors/Serotonin Norepinephrine Reuptake Inhibitors and Serotonin Syndrome.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

SUPERCEDED SUPPLEMENTS

We also note that the following supplemental applications have been superseded by the approval of NDA 20-080/S-036 on February 1, 2006. Therefore, we will not review these supplemental applications but will retain them in our files.

Supplement #:	Letter Date:	Receipt Date:
S-028	3/30/2001	4/2/2001
amended:	9/21/2004	9/22/2004
S-034	12/13/2004	12/14/2004
S-037	1/17/2006	1/19/2006

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 Lana Chen, Regulatory Project Manager, at (301) 796-1056.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20080	SUPPL-38	GLAXOSMITHKLIN E	IMITREX (SUMATRIPTAN SUCCINATE) INJ
NDA-20080	SUPPL-34	GLAXOSMITHKLIN E	IMITREX (SUMATRIPTAN SUCCINATE) INJ
NDA-20080	SUPPL-28	GLAXOSMITHKLIN E	IMITREX (SUMATRIPTAN SUCCINATE) INJ
NDA-20080	SUPPL-37	GLAXOSMITHKLIN E	IMITREX (SUMATRIPTAN SUCCINATE) INJ

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/s/

RUSSELL G KATZ
07/21/2010