DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-626/S-013/ S-015/ S-016

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Christopher J. Stotka, PharmD
Associate Director, Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Stotka:

Please refer to the following Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Imitrex (sumatriptan) Nasal Spray.

SLR	Letter Date	Receipt Date
013	September 21, 2004	September 22, 2004
This "Changes Being Effected" supplemental new drug application provides for the addition of a sentence about possible loss of vision under the WARNINGS: Other Vasopasm-Related Events subsection.		
015	January 17, 2006	January 18, 2006
This "Changes Being Effected" supplemental new drug application provides for the revision of PRECAUTIONS: Nursing Mothers subsection.		
016	June 29, 2006	June 30, 2006
amended:	October 31, 2006	October 31, 2006
amended:	April 11, 2007	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 these supplemental 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

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.

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-20626	SUPPL-16	GLAXOSMITHKLINE	IMITREX (SUMATRIPTAN) NASAL SPRAY 5MG/10
NDA-20626	SUPPL-15	GLAXOSMITHKLINE	IMITREX (SUMATRIPTAN) NASAL SPRAY 5MG/10
NDA-20626	SUPPL-13	GLAXOSMITHKLINE	IMITREX (SUMATRIPTAN) NASAL SPRAY 5MG/10

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
07/21/2010