DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-132/S-014
NDA 20-626/S-007
NDA 20-080/S-030

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 your supplemental new drug applications dated January 31, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imitrex (sumatriptan) tablets, Imitrex (sumatriptan) nasal spray and Imitrex (sumatriptan) injection.

These supplemental applications provide for a change in the wording describing reports of seizure following administration of sumatriptan in the Precautions section:

From: *"There have been rare reports of seizure following administration of sumatriptan. Sumatriptan should be used with caution in patients with a history of epilepsy or structural brain lesions that lower their seizure threshold.*"

To: *"There have been rare reports of seizure following administration of sumatriptan. Sumatriptan should be used with caution in patients with a history of epilepsy or conditions associated with a lowered seizure threshold."*

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert, patient package insert submitted January 31, 2003), which incorporates all of the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental applications are permitted by section 314.70(c) of the regulations to be instituted prior to approval of these supplements. It is understood that the changes, described in the above NDA supplements, have been made.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Lana Chen, R.Ph., Regulatory Project Manager, at (301) 594-5529.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Thomas Laughren
7/28/03 03:48:42 PM
Signed for Russell Katz, M.D.