DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-626/S-006

Glaxo Wellcome
Attention: Judith Babo
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Babo:

Please refer to your supplemental new drug application dated December 3, 2001 (S-006) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imitrex (sumatriptan succinate) Injection.

This supplemental application provides for redesigned carton graphics, similar to those approved for Imitrex Tablets (NDA 20-132/S-012, approved 6/25/01). The supplement also provides minor editorial changes in the package insert and patient package insert.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert, patient package insert, and immediate container and carton labels submitted December 3, 2001, Label Code RL-1005), which incorporates all of the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

Additionally, we have reviewed the content of your supplemental application dated March 30, 2001 (S-005) submitted under "Changes Being Effected". This supplemental new drug application provides for the addition of "Loss of Vision" to the ADVERSE REACTIONS: Postmarketing Experience (Reports for Subcutaneous or Oral Sumatriptan): *Eye* subsection of labeling. The revisions provided in this supplement are incorporated in your December 3, 2001 supplement (S-006). Therefore, supplemental application S-005 has been superceded by the labeling approved in supplemental application S-006 and will be retained in our files.

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 this drug product (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 this NDA 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/

Russell Katz
5/10/02 08:15:19 AM