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*APPLICATION NUMBER:*

**20-132/S-015**

**APPROVAL LETTER**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-132/S-015

Glaxo Group Limited d/b/a GlaxoSmithKline  
Attention: Mary-Kaye Whisler, Ph.D.  
Assistant Director, CMC New Submissions  
Five Moore Drive  
P.O. Box 13398  
Research Triangle Park, NC 27709

Dear Dr. Whisler:

Please refer to your supplemental new drug application dated February 28, 2003 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Imitrex (sumatriptan) tablets.

We acknowledge receipt of your submissions dated March 14, May 16, May 23, and June 20, 2003.

This supplemental new drug application provides for the reformulation of Imitrex Tablets to allow for a modified mechanism for disintegration and dispersion in the stomach. The submission also provides for revised tablet specifications, which include a new HPLC method for *Assay* and *Related substances* and a new *Dissolution* method.

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

The final printed labeling (FPL) must be identical to the submitted labeling, as amended (package insert, patient package insert, immediate container and carton labels submitted February 28, 2003).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-132/S-015." Approval of this submission by FDA is not required before the labeling is used.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

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MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, 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

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/s/

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Russell Katz  
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