DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-583/S-023

GlaxoSmithKline
2301 Renaissance Blvd.
P.O. Box 61540
King of Prussia, PA 19406-2772

Attention: Olivia Pinkett, Ph.D., M.B.A.
Senior Director, GI/Inflammation
U.S. Regulatory Affairs

Dear Dr. Pinkett:

Please refer to your supplemental new drug application dated August 24, 2004, received August 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RELAFEN® (nabumetone), 500 and 750 mg Tablet.

We also acknowledge receipt of your submission dated March 29, 2005, which constituted a complete response to our February 25, 2005, action letter.

This supplemental new drug application proposes revisions to the **CLINICAL PHARMACOLOGY**, **PRECAUTIONS** and **DOSAGE AND ADMINISTRATION** sections of the Relafen Prescribing Information (PI).

Additionally, **WARNINGS: Risk of GI Ulceration, Bleeding, and Perforation with NSAID Therapy** is revised to include oral corticosteroids to the list of items that are risk factors for GI bleeding when combined with NSAID therapy.

Finally, there are editorial changes made throughout the prescribing information conforming to your standard labeling format and the *AMA Manual of Style*.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical, to the package insert submitted March 29, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually please mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-583/S-023**." Approval of this submission by FDA is not required before the labeling is used.

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:

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

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 Paul Z. Balcer, Regulatory Project Manager, at (301) 827 2090.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Sharon Hertz
8/11/05 09:22:36 AM
Signing for Bob Rappaport, MD