DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-444/S-016

GlaxoSmithKline
Attention: Catherine K. Clark
Director, US Regulatory Affairs
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Ms. Clark:

Please refer to your supplemental new drug application dated January 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FLOLAN (epoprostenol sodium) for Injection.

This "Changes Being Effected" supplemental new drug application provides for changes to the **PRECAUTIONS/*General*** subsection to include the following wording:

> FLOLAN is a potent inhibitor of platelet aggregation. Therefore, an increased risk for hemorrhagic complications should be considered, particularly for patients with other risk factors for bleeding (see PRECAUTIONS: Drug Interactions).

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format submitted on January 30, 2008.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Dan Brum, Regulatory Project Manager, at (301) 796-0578.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal 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/

Norman Stockbridge

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