DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022350/S-007

SUPPLEMENT APPROVAL

Bristol-Myers Squibb Company
Attention: Pamela J. Smith, M.D.
Group Director, GRS
P.O. Box 4000
Princeton, NJ 08543

Dear Dr. Smith:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Onglyza (saxagliptin) Tablets 2.5 mg and 5 mg.

We acknowledge receipt of your amendments dated November 4, 2011.

We also refer to our email dated August 4, 2011, requesting submission of a Medication Guide.

This "Prior Approval" supplemental new drug application provides for conversion of the approved patient package insert to a Medication Guide, revisions to the **INDICATIONS AND USAGE, CONTRAINDICATIONS,** and **WARNINGS AND PRECAUTIONS** sections of the Highlights of Prescribing Information section and changes to the **INDICATIONS AND USAGE, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS,** and **PATIENT COUNSELING INFORMATION** sections of the Full Prescribing Information sections of the Onglyza package insert, with information regarding hypersensitivity reactions, including anaphylaxis and angioedema, and acute pancreatitis.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels or carton and immediate container labels submitted on November 4, 2011, as soon as they are available, but no more than 30 days after they are printed.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

It is no longer necessary to submit 15-day expedited reports for all postmarketing cases of pancreatitis, as requested in the July 31, 2009, approval letter for Onglyza. Instead, include in your Periodic Safety Update Reports (PSURs) for Onglyza a detailed analysis of postmarketing reports of pancreatitis and hypersensitivity reactions (including angioedema, anaphylaxis, and Stevens Johnson Syndrome). For these analyses, show cumulative data relative to the date of approval of Onglyza as well as relative to the prior PSUR.

If you have any questions, call Raymond Chiang, Regulatory Project Manager, at (301) 796-1940.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES:

- Package Insert
- Medication Guide
- Container Label – 2.5mg, 30 tablet bottle
- Container Label – 2.5mg, 90 tablet bottle
- Container Label – 5mg, 30 tablet bottle
- Container Label – 5mg, 90 tablet bottle
- Container Label – 5mg, 500 tablet bottle
- Carton Label – 5mg, 28 tablet, contains 4 of the 7 tablet wallets (sample)
- Carton Label – 5mg, 100 tablet, 10 blister cards with 10 tablets each
- Container/Carton Label – 5mg, 7 tablet wallet (sample)

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

/s/

MARY H PARKS
11/15/2011