DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022200/S-015
NDA 022200/S-016
NDA 022200/S-017
NDA 022200/S-018

SUPPLEMENT APPROVAL

ASTRAZENECA AB
C/O ASTRAZENECA PHARMACEUTICALS LP
Attention: Emery Gigger
Regulatory Affairs Director
1 Medimmune Way
Gaithersburg, MD 20878

Dear Mr. Gigger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 24, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Bydureon (exenatide extended-release) for injectable suspension.

We acknowledge receipt of your amendments dated March 31, April 28, 30, May 5, June 19, and September 10, 2015. We also acknowledge receipt of your email dated September 24, 2015, which includes the agreed-upon labeling.

This "Prior Approval" supplemental new drug application proposes to include efficacy and safety data to the Prescribing Information of Bydureon based on following:

NDA Number	Supplement Numbers	Protocols
022200	015	BCB106, *A Randomized, Double-Blind, Parallel-Group, Multicenter Study to Compare the Glycemic Effects, Safety, and Tolerability of Exenatide Once Weekly to Those of Sitagliptin and Pioglitazone in Subjects with Type 2 Diabetes Mellitus Treated With Metformin*
	016	H8O-MC-GWBR (GWBR), *Efficacy of Once-Weekly Exenatide Long-Acting Release and Once-Daily Insulin Glargine in Patients with Type 2 Diabetes Treated with Metformin Alone or in Combination with Sulfonylurea*
	017	H8O-MC-GWCH (GWCH), *Safety and Efficacy of Exenatide Once Weekly Injection versus Metformin, Dipeptidyl Peptidase-4 Inhibitor, or Thiazolidinedione as Monotherapy in Drug-Naïve Patients with Type 2 Diabetes*

NDA Number	Supplement Numbers	Protocols
	018	H8O-MC-GWDE (GWDE), *Safety and Efficacy of Exenatide Once Weekly versus Liraglutide in Subjects with Type 2 Diabetes and Inadequate Glycemic Control Treated with Lifestyle Modification and Oral Antidiabetic Medications in the Bydureon Prescribing Information*

APPROVAL & LABELING

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), 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 that includes labeling changes 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the

product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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 Martin White, M.S., Regulatory Project Manager, at (240) 402-6018.

Sincerely,

{See appended electronic signature page}

Jean-Marc Guettier, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

JEAN-MARC P GUETTIER
09/24/2015