DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22287/S-021/S-022/S-023
NDA 208056/S-01

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENTS

Takeda Pharmaceuticals USA, Inc.
Attention: Valerie Tews, RAC, Manager
Regulatory Affairs Strategy
One Takeda Parkway
Deerfield, Illinois 60015

Dear Ms. Tews:

Please refer to the following supplemental New Drug Applications (sNDA), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dexilant (dexlansoprazole delayed-release capsules) and Dexilant SoluTab (dexlansoprazole delayed-release orally disintegrating tablet).

NDA 22287 Dexilant (dexlansoprazole delayed-release) capsules, 30 mg and 60 mg, submitted on September 30, 2016, provides for the expansion of the current indications to include pediatric patients 12 to 17 years of age:

S/021: healing of all grades of erosive esophagitis (EE)
S/022: maintenance of healed EE and relief of heartburn
S/023: treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (sGERD).

NDA 208056/S01 Dexilant SoluTab (dexlansoprazole delayed-release orally disintegrating tablet), 30 mg, submitted on January 29, 2016, provides for the expansion of the current indications to include pediatric patients 12 to 17 years of age:

- maintenance of healed erosive esophagitis (EE) and relief of heartburn
- treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD).

APPROVAL & LABELING

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

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

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 that include 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 numbers and annual report dates.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

NDA 22287 FULFILLMENT OF POSTMARKETING REQUIREMENTS

These prior approval supplemental new drug applications submission dated September 30, 2015, contained the final reports for the following postmarketing requirements listed in the January 30, 2009, approval letter and modified in the June 17, 2011, supplemental approval letter:

1356-5 Deferred pediatric study under PREA for treating heartburn associated with non-erosive GERD in pediatric patients aged 12 years to 17 years.

1788-1 Deferred study under PREA to evaluate the pharmacokinetics, healing, maintenance of healing, and symptoms of endoscopy-proven erosive esophagitis (EE) in patients 12 years to 17 years of age.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the January 30, 2009, approval letter and June 17, 2011, supplemental approval letter that are still open.

NDA 208056 FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated January 29, 2016, containing a prior approval supplement to expand the indications to include patients 12 years of age and older. The pediatric studies conducted to support product labeling in pediatric patients 12 to 17 years of age utilized dexlansoprazole delayed-release capsules (NDA 22287, Dexilant). Dexilant (dexlansoprazole delayed-release capsules) 30 mg and Dexilant SoluTab (dexlansoprazole orally disintegrating tablets) 30 mg were established to be bioequivalent. We note that you have fulfilled the pediatric study requirements for patients 12 to 17 years of age in supplemental NDA 22287/S021, 022, 023. This prior approval efficacy supplement cross-references NDA 22287 and the following postmarketing requirements listed in the January 26, 2016, approval letter:

3019-2 Deferred study under PREA to evaluate the pharmacokinetics of dexlansoprazole, maintenance of healing, and symptoms of endoscopy-proven erosive esophagitis (EE) in patients 12 years to 17 years of age.

3019-4 Deferred pediatric study under PREA for treating heartburn associated with non-erosive gastroesophageal reflux disease (GERD) in pediatric patients aged 12 year to 17 years.

We have reviewed your submission and conclude that the above requirements were fulfilled.

We remind you that there are postmarketing requirements listed in the January 26, 2016, approval letter that are still open.

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 Maureen Dewey, Regulatory Project Manager, at (301) 796-0845.

Sincerely,

{See appended electronic signature page}

Andrew E. Mulberg, MD, FAAP, CPI
Deputy Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
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/

ANDREW E MULBERG
07/08/2016