DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22287/S-008

SUPPLEMENT APPROVAL

Takeda Global Research & Development Center, Inc.
Attention: Valerie Tews, RAC
Regulatory Strategy Product Manager
One Takeda Parkway
Deerfield, Illinois 60015

Dear Ms. Tews:

Please refer to your Supplemental New Drug Application (sNDA) dated August 16, 2010, received August 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dexilant (dexlansoprazole) delayed release capsules.

We acknowledge receipt of your amendments dated September 17, October 12, October 14, October 19, November 19, 2010, and January, 12, May 3, June 8, and June 14, 2011.

This Prior Approval supplemental new drug application provides for the expansion of the maintenance of healed erosive esophagitis indication to include the relief of heartburn.

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 and with the minor editorial revisions indicated in the enclosed labeling.

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, 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).

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.

We are waiving the pediatric study requirement for ages birth to less than one month for the indication of healing and maintaining healing of all grades of erosive esophagitis (EE) because the necessary studies are impossible or highly impractical. This is because of the low incidence of EE in infants birth to less than one month of age.

We are deferring submission of your pediatric studies for ages 1 month to 17 years for this application for the indication of healing and maintaining healing of all grades of erosive esophagitis (EE) because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

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.

Final Protocol Submission:	March 2012
Study/Trial Completion:	June 2015
Final report submission:	December 2015

1788-2. Deferred study under PREA to evaluate the pharmacokinetic, pharmacodynamic, and safety profiles of dexlansoprazole in patients 1 month to 11 months of age with endoscopy-proven erosive esophagitis (EE).

Final Protocol Submission:	January 2013
Study/Trial Completion:	February 2015
Final Report Submission:	August 2015

1788-3. Deferred study under PREA to evaluate the pharmacokinetics, healing, maintenance of healing, and symptoms of endoscopy-proven erosive esophagitis (EE) in patients 1 year to 11 years of age.

Final Protocol Submission:	January 2013
Study/Trial Completion:	June 2017
Final report submission:	December 2018

1788-4. Deferred study under PREA to evaluate the long-term safety of dexlansoprazole for the healing and maintenance of healing of erosive esophagitis (EE) in pediatric patients 1 month through 11 months of age, who require chronic treatment with dexlansoprazole due to underlying conditions that predispose to chronic gastroesophageal reflux disease and relapsing EE.

Final Protocol Submission:	April 2013
Study/Trial Completion:	April 2019
Final Report Submission:	October 2019

1788-5. Deferred study under PREA to evaluate the long-term safety of dexlansoprazole for the healing and maintenance of healing of erosive esophagitis (EE) in pediatric patients 1 year through 17 years of age, who require chronic treatment with dexlansoprazole due to underlying conditions that predispose to chronic gastroesophageal reflux disease and relapsing EE.

Final Protocol Submission:	April 2013
Study/Trial Completion:	April 2019
Final Report Submission:	October 2019

Submit clinical protocols to your IND 69927 for this product. Submit final study reports to this NDA. Reports of these required pediatric postmarketing studies must be submitted as a new drug application (NDA) or as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from these studies. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated "**Required Pediatric Assessment(s)**" in large font, bolded type at the beginning of the cover letter of the submission.

We have the additional changes to required pediatric assessments included in the original approval of Dexilant (dexlansoprazole) delayed release capsules on January 30, 2009. The changes to the required studies are listed below:

1. We are waiving the original pediatric study requirement in our letter dated January 30, 2009, for treating heartburn associated with non-erosive GERD in pediatric patients aged 1 month to 11 months of age. There is evidence strongly suggesting that the drug would be ineffective in this pediatric age group and that conservative treatment of

symptoms associated with non-erosive GERD is the recommended approach. Therefore, we are releasing you from the postmarketing requirement (PMR 1356-3):

"Deferred pediatric study under PREA for treating heartburn associated with non-erosive GERD in pediatric patients aged 1 month to 11 months."

2. We are releasing you from the requirement for a deferred pediatric study (PMR 1356-1) under PREA to evaluate healing and maintenance of healing of all grades of erosive esophagitis (EE) in pediatric patients 1 year to 11 years. You are being released from the requirement to perform this study because this study is being replaced by a new study required under PREA to evaluate the healing, maintenance of healing, and symptoms of endoscopy-proven erosive esophagitis (EE) in patients 1 year to 11 years of age.

3. We are releasing you from the requirement for a deferred pediatric study (PMR 1356-2) under PREA to evaluate healing and maintenance of healing of all grades of erosive esophagitis (EE) in pediatric patients 12 years to 17 years. You are being released from the requirement to perform this study because this study is being replaced by a new study required under PREA to evaluate the healing, maintenance of healing, and symptoms of endoscopy-proven erosive esophagitis (EE) in patients 12 years to 17 years of age.

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.

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
06/17/2011