DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202067/S-5
NDA 203993/S-7

SUPPLEMENT APPROVAL

Lundbeck Pharmaceuticals, LLC
Attention: Ryan Kohl
Sr. Associate, US Regulatory Affairs
Six Parkway North, Suite 400
Deerfield, IL 60015

Dear Mr. Kohl:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received December 15, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Onfi (clobazam) tablet and oral suspension.

These Prior Approval supplemental new drug applications provide for changes to Sections 8.1, 8.2, and 8.3 (Use In Specific Populations: Pregnancy; Lactation; and Females and Males of Reproductive Potential, respectively), and Section 17 (Patient Counseling Information) of the full prescribing information to comply with the "Final Rule: Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling," published December 4, 2014. They also provide for the following additional changes: the addition of "opioids" to Section 10.1 (Overdosage: Signs and Symptoms of Overdosage) as an example of another central nervous system depressant, and the addition of results from completed carcinogenicity studies in mice and rats (which were done to fulfill Postmarketing Requirements 1827-1 and 1827-2) to Section 13.1 (Nonclinical Toxicology: Carcinogenesis, Mutagenesis, Impairment of Fertility).

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.

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, Medication Guide, Instructions for Use), 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 these NDAs, 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 these supplemental applications, 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 (which includes new salts and new fixed combinations), 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 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.

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 Harold Sano, PharmD, MBA, Regulatory Project Manager, at (301) 796-2429.

Sincerely,

{See appended electronic signature page}

Alice Hughes, MD
Deputy Director for Safety
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

ALICE HUGHES
06/15/2018