



NDA 21436 / S-037
NDA 21866 / S-022
NDA 21713 / S-029
NDA 21729 / S-021

SUPPLEMENT APPROVAL

Otsuka Pharmaceutical Development & Commercialization, Inc.
Attention: David Goldberger, R.Ph., RAC
Vice President, Global Regulatory Affairs
2440 Research Blvd.
Rockville, MD 20850

Dear Mr. Goldberger:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received May 8, 2013, submitted under section 505(b) of the Federal Food Drug, and Cosmetic Act (FDCA) for Abilify (aripiprazole) tablets, oral solution, orally disintegrating tablets, and injectable formulation.

These “Prior Approval” supplemental new drug applications provide for revisions to the Nursing Mothers section of labeling and the Medication Guide.

We have completed our review of these supplemental applications. 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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and Medication Guide) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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.

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Also within 14 days, amend all pending supplemental applications for this NDA, including pending CBE supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(1)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Sonny Saini, Pharm.D., MBA, Regulatory Project Manager, at (301) 796-0532.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
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/

MITCHELL V Mathis
07/30/2013