DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021436/S-027 **SUPPLEMENT APPROVAL**

Otsuka Pharmaceutical Company, Ltd.
Attention: David Goldberger, R.Ph.
Senior Director, Regulatory Affairs
Otsuka Pharmaceutical Development and Commercialization, Inc.
100 Overlook Center, 1st Floor
Princeton, NJ 08540

Dear Mr. Goldberger:

Please refer to your supplemental new drug application dated January 21, 2009, received January 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ABILIFY (aripiprazole) tablets 2mg, 5mg, 10mg, 15mg, 20mg and 30mg.

We acknowledge receipt of your submissions dated May 21, 2009, August 10, 2009, September 11, 2009, October 8, 2009, October 26, 2009, November 10, 2009, and November 18, 2009.

This "Prior Approval" supplemental new drug application provides for the use of ABILIFY (aripiprazole) for the treatment of irritability associated with autistic disorder in pediatric patients (aged 6 to 17 years).

We have completed our review of this 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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm155657.htm that is identical to the enclosed agreed-upon labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, **"SPL for approved NDA 021436/ S-027."**

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 0 to 5 years in the treatment of irritability associated with autistic disorder because studies are highly impractical due to the low incidence of this disease state in these age ranges.

We are deferring submission of your pediatric studies for ages 6 to 16 years for the maintenance treatment of irritability associated with autistic disorder until November 21, 2014 because this product is ready for approval for use in the acute pediatric treatment of irritability associated with autistic disorder and the pediatric maintenance 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.

1570-1 A deferred pediatric study under PREA for a maintenance treatment study to obtain long-term efficacy and safety data in patients ages 6-16 years.

Final Protocol Submission Date:	by November 21, 2010
Trial Completion Date:	by November 21, 2013
Final Report Submission:	by November 21, 2014

Submit all clinical protocols to your IND for this product. Submit all final reports to your NDA 21-436. Use the following designator to prominently label all submissions and refer to PMC set number **1570**:

Required Pediatric Assessment(s)

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B-05
Rockville, MD 20857

MEDICATION GUIDE

We note that ABILIFY has an issue specific (suicidality) Medication Guide. We request that you submit a comprehensive Medication Guide that incorporates all relevant safety information related to this drug to the Agency for review within six months of the date of this letter.

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, contact CDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301)796-4158.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure (Content of Labeling)

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21436	SUPPL-27	OTSUKA PHARMACEUTICAL CO LTD	ABILIFY (ARIPIPRAZOLE) 10/15/20/30MG

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

/s/

THOMAS P LAUGHREN
11/19/2009