IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

Otsuka Pharmaceutical Co., Ltd., et al.,	*	
Plaintiffs,	*	
v.		CIVIL ACTION NO.
	*	
Sylvia Mathews Burwell, et al.,		
Defendants.		

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MOTION TO EXPEDITE PROCEEDINGS AND MEMORANDUM IN SUPPORT AND REQUEST FOR IMMEDIATE SCHEDULING CONFERENCE

Plaintiffs Otsuka Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Development & Commercialization, Inc., and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") respectfully move to expedite proceedings in this case. Otsuka filed its complaint herein on March 24, 2015, and on the same day Otsuka filed a case dispositive motion for summary judgment. Otsuka seeks an expedited briefing and hearing schedule to have this case resolved on the merits prior to April 20, 2015, to avoid the risk of irreparable harm. As explained below, without a final decision by this Court before April 20, 2015, Otsuka will be significantly and irreparably harmed. In support of its motion, Otsuka states as follows:

1. In this case, Otsuka challenges actions of the defendant U.S. Food and Drug Administration ("FDA"). The case involves no disputed issues of fact as the factual record has been established at the agency. The case involves only questions of law (statutory construction), precisely the kinds of questions the Court routinely resolves on motions for summary judgment.

2. In the absence of a decision in this case on or before April 20, 2015, Otsuka faces the risk of irreparable harm. FDA is expected to approve generic versions of Otsuka's critically important brand drug Abilify on April 20, 2015. Once generics reach the market, the harm to Otsuka cannot be undone.

3. At the moment of expected generic launch on April 20, 2015 (when Otsuka's current patent and regulatory protection expire and FDA will, it is expected, approve the generics), Otsuka will be irreparably harmed. Abilify is one of the largest selling prescription drug products in the U.S. and is of enormous importance to the company. The entry of generics will mean the loss of statutory exclusivity, eroded prices and market share, diminished research and educational efforts, loss of goodwill in physicians and patients, and a devastating impact on Otsuka's U.S. operations, including its Abilify sales force. This harm can be avoided if the Court expedites these proceedings.

4. Given the risk of irreparable harm to Otsuka as of April 20, the alternative to proceeding directly and expeditiously to Otsuka's motion for summary judgment (and any cross-motion that FDA may file) is for Otsuka to move for temporary and/or preliminary injunctive relief and thereafter to move for summary judgment. Otsuka respectfully submits that its proposed procedure of proceeding directly to the merits is more efficient, in the interest of judicial economy, and the proper way to proceed in this case which presents only questions of law.

5. As set forth in Otsuka's motion for summary judgment, count one of Otsuka's complaint challenges FDA's reversal of its original supplemental new drug approval that approved a new indication for Otsuka's brand drug Abilify for the treatment of *pediatric* patients with Tourette's Disorder. FDA reversed itself, "corrected" that approval, and granted a new approval for which there is no supporting clinical trial data. FDA's "correction" approved Abilify for the treatment of Tourette's Disorder in the population at large (*i.e.*, without limitation as to the patient's age), again an indication for which there is no substantiating clinical data.

6. FDA deliberately and intentionally reversed its original approval of a pediatric indication to attempt to clear the way for generic approvals on April 20, 2015. This action

threatens to harm irreparably Otsuka. Otsuka challenges FDA's "corrected" approval as arbitrary, capricious, contrary to law, and an abuse of discretion. 5 U.S.C. § 706(2)(A). FDA's action was contrary to its statutory authority under the federal Food, Drug, and Cosmetic Act and without factual or evidentiary support. FDA's improper rationale for granting a far broader approval than its original approval was to seek to preclude Otsuka from receiving the benefits of a seven-year period of market exclusivity to which it would be entitled pursuant to FDA's original approval limited to pediatric patients.

7. Count two of Otsuka's complaint assumes, without conceding, the validity of FDA's abrupt reversal of position and its adoption of the "corrected" approval. Notwithstanding FDA's broadened approval, FDA is barred as a matter of law from approving any generic versions of Abilify pending the expiration of Otsuka's seven-year period of orphan drug market exclusivity for the new indication. FDA's attempt to deny Otsuka the market exclusivity that Congress granted and to which Otsuka is entitled by granting the broadened "corrected" approval failed in any event.

8. Otsuka proposes the following proposed schedule:

March 31:	Filing of administrative record
April 7:	FDA Opposition to Plaintiffs' motion for summary judgment and/or filing of any cross-motion
April 13:	Otsuka's Reply
April 14, 15, or 16:	Hearing

9. This schedule provides the defendants with adequate time to prepare the administrative record and the normal fourteen days to file its opposition. Local Rule 105(2)(a). It also affords the Court an opportunity to hear oral argument prior to April 20, 2015.

A proposed Order is attached.

Respectfully submitted,

Dated: March 24, 2015

/s/ Ralph S. Tyler

Ralph S. Tyler (Bar No. 01747)
rtyler@venable.com
Maggie T. Grace (Bar No. 29905)
mtgrace@venable.com
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
(410) 244-7400
Fax: (410) 244-7742

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that the above motion to expedite was served electronically on counsel for FDA this 24th day of March, 2015 as follows:

Elizabeth H. Dickinson, Esq.
Chief Counsel
U.S. Food and Drug Administration
Elizabeth.Dickinson@FDA.HHS.gov

Annamarie Kempic, Esq.
Deputy Chief Counsel, Litigation
U.S. Food and Drug Administration
Annamarie.Kempic@FDA.HHS.gov

/s/ Ralph S. Tyler
Ralph S. Tyler

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SCHEDULING ORDER

Having reviewed plaintiffs' motion to expedite and any opposition thereto and good cause for expedited proceedings herein having been shown, plaintiffs' motion is hereby **GRANTED** and the following schedule shall govern further proceedings herein:

March 31, 2015:	Defendants shall file the administrative record
April 7, 2015:	Defendants shall file their opposition to plaintiffs' motion for summary judgment (filed March 24, 2015) and any cross-motions
April 13, 2015:	Plaintiffs shall file any reply and opposition to any cross-motions
April __, 2015:	Hearing on plaintiffs' motion for summary judgment and any cross-motions

SO ORDERED this _____ day of March, 2015.

_____
U.S. District Judge