

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

_____)	
TEVA PHARMACEUTICALS USA, Inc.)	
)	
Plaintiff,)	
)	
v.)	
)	
KATHLEEN SEBELIUS, in her official capacity)	
as Secretary of Health and Human Services;)	Case No. 1:09-cv-01111-GK
)	
MARGARET HAMBURG, M.D., in her official)	
capacity as Commissioner of Food and Drugs;)	
)	
UNITED STATES FOOD AND DRUG)	
ADMINISTRATION,)	
)	
Defendants.)	
_____)	

**PLAINTIFF TEVA PHARMACEUTICALS USA, INC.’S MOTION FOR
PRELIMINARY INJUNCTIVE RELIEF**

Plaintiff Teva Pharmaceuticals USA, Inc. (“Teva”) respectfully submits this motion for preliminary injunctive relief declaring that FDA’s Delisting Rule is in excess of FDA’s statutory authority, arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law, and that Teva has not, as of the date of the Court’s order, forfeited its right to 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I) by virtue of the ‘075 patent’s purported delisting, and compelling Defendants Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, Margaret Hamburg, M.D., in her official capacity as Commissioner of Food and Drugs, and the United States Food and Drug Administration (collectively, “FDA”) to proceed on Teva’s ANDA Nos. 07-6958 and 07-7157 in a manner not inconsistent with this Court’s ruling.

The grounds for the present Motion are fully set forth in the accompanying Memorandum of Points and Authorities and Declaration of David Marshall.

Dated: June 19, 2009

Respectfully submitted,

/s Michael D. Shumsky

Jay P. Lefkowitz, P.C. (D.C. Bar No. 449280)

Michael D. Shumsky (D.C. Bar No. 495078)

Gregory L. Skidmore (D.C. Bar No. 974024)

KIRKLAND & ELLIS LLP

655 Fifteenth Street NW, Suite 1200

Washington, DC 20005

(202) 879-5000

(202) 879-5200 fax

Counsel for Teva Pharmaceuticals USA, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies that on this 19th day of June, 2009, he caused a copy of the foregoing **MOTION FOR PRELIMINARY INJUNCTIVE RELIEF** to be served upon the following attorneys by electronic mail:

Eric Blumberg
Elizabeth Dickinson
Shoshanna Hutchinson
Office of the Chief Counsel
Food and Drug Division
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857
(301) 827-8579

Counsel for the Federal Defendants

/s Michael D. Shumsky
Michael D. Shumsky
Counsel for Teva Pharmaceuticals USA, Inc.