UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ACTAVIS ELIZABETH LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 09-CV-00362 (RMC)
	)	
CHARLES E. JOHNSON, *et al.*,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' UNOPPOSED
MOTION TO STAY PROCEEDINGS

Defendants hereby move to stay all proceedings in this case until the Food and Drug Administration ("FDA" or "agency") completes its administrative consideration of issues raised by plaintiff Actavis Elizabeth LLC ("Actavis") to the agency. On January 29, 2009, Actavis filed an abbreviated new drug application ("ANDA") for lisdexamfetamine dimesylate capsules, a generic version of brand-name Vyvanse, a drug used to treat attention deficit hyperactivity disorder. On that same day, Actavis requested that the agency rescind its determination that Vyvanse was a new chemical entity ("NCE") and thereby entitled to five years of exclusivity, which has the effect of barring the submission of an ANDA for a generic version of Vyvanse. On February 6, 2009, Actavis submitted a more detailed "legal brief" arguing that the agency should reconsider its decision. Also on February 6, 2009, FDA refused to accept Actavis's ANDA on the ground that FDA had granted five-year exclusivity to Vyvanse.

Actavis sued FDA on February 24, 2009, challenging FDA's February 6, 2009 decision refusing to file Actavis's ANDA, before the agency had a meaningful opportunity to consider the arguments that Actavis had raised in its February 6, 2009 brief concerning the application of the

governing statute and regulation (21 U.S.C. § 355(j)(5)(F)(ii) and 21 C.F.R. § 314.108) to lisdexamfetamine. FDA has determined that these issues should be considered administratively through a public process.[1] Accordingly, on April 13, 2009, the agency stayed its decision refusing to accept Actavis's ANDA[2] and opened a docket (Docket No. FDA-2009-N-0184) to solicit public comment on the issues raised by Actavis. The substantive issues in this litigation are under active consideration by the agency. FDA anticipates that the docket will close with an agency decision by September 25, 2009.

Actavis does not oppose staying the litigation until the administrative process has been completed. FDA will advise the Court promptly of its administrative determination in this matter and will, in any event, submit a status report to the Court on or before September 25, 2009.

---

[1] In its preamble proposing the applicable regulation, 21 C.F.R. § 314.108, FDA stated that challenges to its exclusivity determinations should be made pursuant to 21 C.F.R. § 10.25, which allows interested persons to petition the agency. *See* 54 Fed. Reg. 28871, 28901-902 (July 10, 1989). FDA indicated that such challenges should be part of a public process to give constructive notice to all applicants who could be affected by the determination. *Id.*

[2] FDA has merely stayed its action refusing to file Actavis's ANDA. It has not accepted the ANDA for filing and does not anticipate taking any further action on Actavis's ANDA until it has made a final administrative decision on the issues raised by Actavis.

Accordingly, federal defendants respectfully request that the Court enter the attached order staying all proceedings in this case until FDA has issued an administrative decision in Docket No. FDA-2009-N-0184.

Respectfully submitted,

Of Counsel:

DAVID S. CADE
Acting General Counsel

JEFFREY M. SENGER
Acting Associate General Counsel,
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

WENDY S. VICENTE
Associate Chief Counsel

U.S. Dept. of Health & Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, MD 20857
Tel: (301) 827-7138

MICHAEL F. HERTZ
Acting Assistant Attorney General

EUGENE M. THIROLF
Director
Office of Consumer Litigation

/s/
ANDREW E. CLARK
Senior Litigation Counsel
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Tel: (202) 307-0067
Fax: (202) 514-8742
andrew.clark@usdoj.gov

Dated: April 13, 2009

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing Unopposed Motion to Stay Proceedings to be served via the District Court's electronic filing (ECF) system upon:

John DeQ. Briggs, III
AXINN, VELTROP & HARKRIDER, LLP
1330 Connecticut Avenue, NW
Washington, D.C. 20036
Counsel for Plaintiff Actavis Elizabeth, LLC

Chad A. Landmon
Jo Anne M. Kokoski
AXINN, VELTROP & HARKRIDER, LLP
90 State House Square
Hartford, CT 06103
Counsel for Plaintiff Actavis Elizabeth, LLC

this 13th day of April, 2009.

/s/
Andrew E. Clark