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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

VALEANT PHARMACEUTICALS INTERNATIONAL, Plaintiff, v. MICHAEL O. LEAVITT, in his official capacity as Secretary of the U.S. Department of Health and Human Services, and ANDREW C. VON ESCHENBACH, M.D., in his official capacity as Commissioner of the Food and Drug Administration, Defendants.	NO. SA CV 08-00449-AG DEFENDANTS' *EX PARTE* APPLICATION TO STAY PROCEEDINGS AND REFER MATTER TO AGENCY; DECLARATION IN SUPPORT THEREOF No Hearing Scheduled Before the Honorable Andrew J. Guilford

Federal Defendants hereby apply for an Order referring this matter back to the Food and Drug Administration ("FDA") and holding judicial review in abeyance pending FDA's administrative reconsideration of this matter. As set forth more fully in the accompanying memorandum of points and authorities and declaration, FDA has initiated administrative reconsideration of Spear's abbreviated new drug application ("ANDA") for 5% fluorouracil ("5-FU") cream pursuant to 21 C.F.R. § 10.33(a) & (h). Concomitantly therewith, Intervenor-Defendant Spear Pharmaceuticals, Inc. ("Spear") has agreed to the entry of an administrative stay of its ANDA approval under 21 C.F.R. § 10.35(a). *See* Clark Declaration Exhibit A (Administrative Reconsideration and Stay of Action); Exhibit B (Letter from Steven Lieberman, May 14, 2008). FDA hopes to conclude its administrative reconsideration by May 30, 2008. In the interim, consistent with agency regulations, FDA requests that the Court refer the matter back to the agency and hold judicial review of the challenged agency action in abeyance pending the completion of FDA's administrative reconsideration process. *See* 21 C.F.R. § 10.33(h).

Because Spear's ANDA approval is stayed through May 30, 2008, and Spear may not sell, market, or ship its product during that period, Plaintiff Valeant Pharmaceuticals International ("Valeant") will suffer no harm during the pendency of FDA's administrative reconsideration.

On May 14, 2008, defendants' counsel contacted counsel for Valeant and Spear concerning this application. Spear's counsel indicated that Spear did not oppose the application. Valeant's counsel indicated that Valeant would oppose the application. Clark Declaration ¶ 4.

Pursuant to Local Rule 7-19, Federal Defendants set forth below the identity of Valeant's counsel as follows:

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Pursuant to Local Rule 7-19, Federal Defendants set forth below the identity of Spear's counsel as follows:

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DATED: May 14, 2008

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U.S. Dept. of Health & Human Services
Office of the General Counsel

MEMORANDUM OF POINTS AND AUTHORITIES

On April 25, 2008, Valeant filed an Application for a Temporary Restraining Order ("TRO"), seeking an order suspending FDA's approval of Spear's ANDA for its 5% fluorouracil ("5-FU") cream. On May 1, 2008, this Court granted a stay of the TRO proceedings until May 14, 2008, based on FDA's identification of an issue in the administrative record that required agency review and consideration, and Spear's commitment to the Court to suspend marketing, sales and shipment activities for the duration of the stay. As of this date, however, FDA has not yet reached a final determination concerning the previously identified administrative record issue. Moreover, in the course of its review, FDA identified an additional issue concerning Spear's ANDA which, in the agency's judgment, necessitates administrative reconsideration of the ANDA approval.[1]

Accordingly, on May 14, 2008, FDA initiated administrative reconsideration of Spear's ANDA pursuant to 21 C.F.R. § 10.33(a) & (h). Concomitantly therewith, Spear has agreed to the entry of an administrative stay of its ANDA approval under 21 C.F.R. § 10.35(a), as well as the suspension of all sales, marketing, and shipping of its Fluorouracil product. *See* Clark Declaration Exhibit A (Administrative Reconsideration and Stay of Action); Exhibit B (Letter from Steven Lieberman, May 14, 2008). FDA hopes to conclude its administrative reconsideration by May 30, 2008, and anticipates that it will be prepared on that date to inform the Court about its decision regarding the administrative reconsideration. In the interim, consistent with agency regulations, FDA requests that the Court refer the matter back to the agency and hold its review in abeyance pending the completion of FDA's administrative reconsideration process. *See* 21

[1] Although this issue concerns whether FDA required the submission of all necessary and appropriate scientific information in support of approval of Spear's ANDA, it is unrelated to the issues raised by Valeant in its TRO motion.

C.F.R. § 10.33(h).[2] FDA will inform the Court and the parties if it concludes its administrative reconsideration sooner than May 30, 2008, and determines that the stay should be dissolved before that date.

Valeant will suffer no harm during the pendency of FDA's reconsideration. Indeed, Valeant has represented to this Court that "[t]he only way for the FDA to moot Valeant's TRO application would be to suspend or stay approval of Spear's ANDA application pursuant to 21 C.F.R. § 10.35(a)." Valeant's Opp. to Stay at 5 (filed May 1, 2008). Because FDA has now stayed approval of Spear's ANDA 77-524 through May 30. 2008, and prohibited all marketing, sales and shipment of product during the pendency of the administrative stay, Valeant's TRO motion has been mooted until that date. Furthermore, because FDA's reconsideration could affect the approval status of Spear's ANDA, it is in the best interest of the parties and consistent with principles of judicial economy to stay any further litigation until that date.

Accordingly, pursuant to 21 C.F.R. § 10.33(h), FDA respectfully requests that the Court refer this matter back to FDA and/or hold all proceedings in this case in abeyance until the conclusion of FDA's administrative reconsideration.

FDA counsel has consulted with counsel for Valeant and Spear concerning this application. Spear's counsel stated that Spear does not oppose the application. Valeant's counsel stated that Valeant would oppose the application. Clark Declaration ¶ 4.

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[2] 21 C.F.R. § 10.33(h) provides: "The Commissioner may initiate the reconsideration of all or part of a matter at any time after it has been decided or action has been taken. If review of the matter is pending in the courts, the Commissioner may request that the court refer the matter back to the agency or hold its review in abeyance pending administrative reconsideration. The administrative record of the proceeding is to include all additional documents relating to such reconsideration."

For the foregoing reasons, Federal Defendants respectfully request that the Court grant this application.

DATED: May 14, 2008

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U.S. Dept. of Health & Human Services
Office of the General Counsel

DECLARATION OF ANDREW E. CLARK

I, Andrew E. Clark, under penalty of perjury do represent the following:

1. I am Senior Trial Counsel in the Office of Consumer Litigation in the United States Department of Justice, 450 5th St., N.W., Washington, D.C. 20001. I am one of the attorneys assigned to represent the federal defendants in the above-captioned case.

2. I am informed that, on May 14, 2008, FDA initiated administrative reconsideration of, and stayed approval of, Spear Pharmaceuticals Inc.'s (Spear) Abbreviated New Drug Application (ANDA) 77-524 for 5-fluorouracil. *See* Exhibit A annexed hereto (Administrative Reconsideration and Stay of Action).

3. I am also informed that Spear has agreed to the above-referenced administrative stay and has committed that it will not market, sell or ship its fluorouracil product until the earlier of noon (EDT) on May 30, 2008, or dissolution of the administrative stay. *See* Exhibit B annexed hereto (Letter from Steven Lieberman, May 14, 2008).

4. As set forth in our Ex Parte Application, I telephoned counsel for Valeant and Spear on May 14, 2008, to advise them of this application and seek their position thereon. Spear's counsel indicated that Spear did not oppose the application. Valeant's counsel subsequently spoke with Eugene Thirolf of this Office and indicated that Valeant would oppose the application.

5. I declare under penalty of perjury that the statements are true and correct.

Dated this 14th day of May, 2008, in Washington, D.C.

/s/
Andrew E. Clark
Senior Trial Counsel
Office of Consumer Litigation
United States Department of Justice