UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HI-TECH PHARMACAL CO., INC. Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civil Action No. 08-1495 (JDB)

FEDERAL DEFENDANT'S STATUS REPORT

On October 10, 2008, this Court denied the Motion for Preliminary Injunction filed by plaintiff Hi-Tech Pharmacal Co., Inc. ("Hi-Tech"). The Court also directed the parties to appear for a status conference on October 28, 2008, at 10:00 AM, if the Food and Drug Administration ("FDA") did not decide the exclusivity forfeiture question on or before October 24, 2008. FDA now provides this status report to inform the Court and the parties of the expected timing of FDA's decision.

Following careful consideration of the Court's October 10, 2008, Memorandum Opinion and Order, the FDA respectfully gives notice of its intent to issue its exclusivity forfeiture decision and any appropriate abbreviated new drug application ("ANDA") approval(s) at the status conference on October 28, 2008, which will be more than twelve hours after the filing of this document. FDA will not make a decision on whether Hi-Tech has forfeited generic exclusivity in advance of the decisions on approval of the pending ANDAs. The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the "MMA")

includes numerous forfeiture provisions, see 21 U.S.C. § 355(j)(5)(D), and FDA recognizes that many ANDA sponsors would prefer advance notice, at their convenience, of whether they or another applicant will be deemed to have forfeited their rights under any of these myriad provisions. Making an advance decision on generic exclusivity, however, would result in FDA making decisions in piecemeal fashion, and FDA could be inundated with such requests from ANDA sponsors. In addition, FDA would be unable to fully explain the basis for an advance exclusivity decision since many details of ANDAs are non-public until approval, and judicial review would thus be similarly circumscribed. FDA's decision not to issue an advance, potentially advisory decision is also consistent with Congress's choice to vest FDA with the authority to take and give effect to its actions, such as approving drugs, subject to subsequent challenge under the Administrative Procedure Act. Cf. Mylan v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000) (the government has an "interest in giving immediate force to an agency's orders and an interest in the authority and finality of [an] agency decision.").

FDA expects that there will be an ANDA ready for final approval at 10:00 AM on October 28, 2008, and counsel for FDA intends to bring FDA's exclusivity decision and any ANDA product approval document(s) to the status conference set for that time, and communicate the substance of its decision to the Court and the parties for the first time at that conference while also issuing any product approval(s). To date, FDA has tentatively approved two ANDAs for generic Cosopt -- Hi-Tech's and Apotex's. If any other generic applicant becomes eligible for tentative approval before October 28, 2008, FDA will issue a tentative approval letter, and will inform this Court and the parties of the fact of the tentative approval. FDA will take no position on another party's request on October 28, 2008, for an order maintaining the status quo ante for a

brief period by enjoining the marketing of generic Cosopt to enable this Court to review FDA's decision while deciding any motions for emergency relief.

Dated: October 24, 2008

Respectfully submitted,

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