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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0125]

Determination That DEXEDRINE (Dextroamphetamine Sulfate) Oral Solution, 5 Milligrams per 5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 milligrams (mg) per 5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dextroamphetamine sulfate oral solution, 5 mg/5 mL.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously

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approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, is the subject of approved ANDA 83–902 held by GlaxoSmithKline (GSK). DEXEDRINE (dextroamphetamine sulfate) oral solution is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). GSK's ANDA 83–902 was originally approved in 1976 and was discontinued in 1988. Lachman Consultant Services, Inc., submitted a citizen petition dated March 17, 2006 (Docket No. 2006P–0125/CP1), under 21 CFR 10.30, requesting that the agency determine, as described in § 314.161, whether DEXEDRINE

(dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA has determined that GSK's DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, we note that DEXEDRINE (dextroamphetamine sulfate) is available in an extended release capsule form and is a widely used product that has been marketed for many decades in many dosage forms. Neither the petition nor any comment to the petition identified evidence suggesting that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was withdrawn for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA determines that GSK's DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DEXEDRINE (dextroamphetamine sulfate) oral solution, 5 mg/5 mL, may be approved by the agency as long as they meet all relevant legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug

products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 30, 2007.

Randall W. Lutter,
Deputy Commissioner for Policy.

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