and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, the Federal Records Act of 1950, as amended, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook, CMS Information Security Handbook, and the National Archives and Records Administration's General Record Schedules and CMS' Records Schedules.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 15 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Chronic Care Policy Group, Centers for Medicare Management, CMS, Mail Stop C5–09–16, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system include data collected from HCPCS applications, submitted by the individuals who voluntarily apply for HCPCS Level II Code modifications.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–15250 Filed 8–6–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0462]

Determination That PREVACID NAPRAPAC (Copackaged Lansoprazole Delayed-Release 15–Milligram Capsules and Naproxen 250–Milligram Tablets) 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 PREVACID NAPRAPAC 250 (copackaged lansoprazole delayed-release 15-milligram (mg) capsules and naproxen 250-mg tablets) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for copackaged lansoprazole delayed-release 15-mg capsules and naproxen 250-mg tablets.

FOR FURTHER INFORMATION CONTACT: Marguerita B. Sims, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5041.

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 approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an 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.

PREVACID NAPRAPAC 250 is the subject of NDA 21–507 held by Tap Pharmaceuticals, Inc. (TAP). PREVACID NAPRAPAC 250 is a copackaged drug product that contains Prevacid (lansoperazole) 15-mg delayed-release capsules (a proton-pump inhibitor) and Naprosyn (naproxen) 250-mg tablets (a nonsteroidal anti-inflammatory drug product (NSAID) with analgesic and antipyretic properties). PREVACID NAPRAPAC 250 is indicated for reducing the risk of NSAID-associated gastric ulcers in patients with a history of documented gastric ulcer(s) who require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, and/or ankylosing spondylitis. TAP's PREVACID NAPRAPAC 250 was discontinued in October 2006.

In a citizen petition received on November 13, 2006 (Docket No. 2006P–0462/CP1), submitted under 21 CFR 10.30 and in accordance with § 314.161, Robert W. Pollock of Lachman

Consultant Services, Inc., requested that FDA determine whether PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined previously, FDA has determined that TAP's PREVACID NAPRAPAC 250 was not withdrawn from sale for reasons of safety or effectiveness. In support of this finding, the agency notes that a higher strength of PREVACID NAPRAPAC 250 [PREVACID NAPRAPAC 500 (15 mg/500 mg)] is currently being marketed. In addition, the petitioner identified no data or information suggesting that PREVACID NAPRAPAC 250 was withdrawn from sale for reasons of safety or effectiveness. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records concerning the withdrawal, FDA found no indication that the decision not to commercially market PREVACID NAPRAPAC 250 was a result of any safety or effectiveness concerns regarding the product. Accordingly, the agency will continue to list PREVACID NAPRAPAC 250 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 PREVACID NAPRAPAC 250 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.

[FR Doc. E7–15233 Filed 8–6–07; 8:45 am]

BILLING CODE 4160–01–S

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 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