CMS–R–240 Prospective Payments for Hospital Outpatient Services

CMS–10164 Medicare EDI Enrollment Form and EDI Registration

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Prospective Payments for Hospital Outpatient Services; *Use:* Section 1833(t) of the Act, as added by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Information from the reports required under sections 413.65(b)(3) and (c) is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services, but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based. *Form Number:* CMS–R–240 (OMB control number: 0938–0798); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 750; *Total Annual Responses:* 13,649,150; *Total Annual Hours:* 680,920 (For policy questions regarding this collection contact Emily Lipkin at 410–786–3633.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Medicare EDI Enrollment Form and EDI Registration; *Use:* The Congress, recognizing the need to simplify the administration of health care transactions, enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104–191, on August 21, 1996. Title II, Subtitle F of this legislation directs the Secretary of the Department of Health and Human Services to develop unique standards for specified electronic transactions and code sets for those transactions. The purpose of this Subtitle is to improve the Medicare and Medicaid programs in particular and the efficiency and effectiveness of the health care industry in general through the establishment of standards and requirements to facilitate the electronic transmission of certain health information. This Subtitle also requires that the Secretary adopt standards for financial and administrative transactions, and data elements for those transactions to enable health information to be exchanged electronically. The Standards for Electronic Transactions final rule, 45 CFR part 162 Subpart K § 162.1101 through Subpart R § 162.1802, (hereinafter referred to as ''Transactions Rule'') published August 17, 2000 adopted standards for health care transactions and code sets. Subsequent to the Transactions Rule, CMS–0003–P and CMS–0005–P proposed modifications to the adopted standards essential to permit initial implementation of the standards throughout the entire healthcare industry.

Currently, Medicare contractors have a process in place to enroll providers for electronic billing and other EDI transactions. In support of the HIPAA Transactions Rule, the purpose of this Paperwork Reduction Act (PRA) request is to establish a common form that is sufficient to address all HIPAA transactions. *Form Number:* CMS–10164 (OMB control number: 0938–0983); *Frequency:* Hourly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 193,268; *Number of Responses:* 193,268; *Total Annual Hours:* 64,423. (For policy questions regarding this collection, contact Matt Klischer at 410–786–7488.)

Dated: November 6, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–24592 Filed 11–8–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4099]

Tedor Pharma, Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of December 10, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040747	Benzphetamine Hydrochloride (HCl) Tablets, 25 milligrams (mg) and 50 mg.	Tedor Pharma, Inc., 400 Highland Corporate Dr., Cumberland, RI 02864.
ANDA 062356	Gentamicin Sulfate Injection USP, Equivalent to (EQ) 10 mg base/milliliter (mL) and EQ 40 mg base/mL.	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 074097	Isoflurane USP, 99.9%	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 076484	Ciprofloxacin Injection USP, 200 mg/20 mL and 400 mg/40 mL.	Fresenius Kabi USA, LLC.
ANDA 080504	Epinephrine and Lidocaine HCl Injection, 0.01 mg/mL; 2% and 0.02 mg/mL; 2%. Lidocaine HCl Injection, 2%.	Belmora LLC, 2231 Crystal Dr., #1000, Arlington, VA 22202.
ANDA 083559	Mepivacaine HCl Injection, 3%	Do.
ANDA 084315	Dexamethasone Acetate Injectable Suspension USP, EQ 8 mg base/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 084850	Levonordefrin and Mepivacaine HCl Injection, 2%; 0.05 mg/mL.	Belmora LLC.
ANDA 086389	Lidocaine HCl Viscous Oral Topical Solution USP, 2%	International Medication Systems, Ltd., 1886 Santa Anita Ave., South El Monte, CA 91733.
ANDA 087863	Choledyl SA (oxtriphylline) Extended-Release Tablets USP, 400 mg.	Warner Chilcott Co., LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 10, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on December 10, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24605 Filed 11–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–2506]

Determination That AXIRON (Testosterone) Transdermal Metered Solution, 30 Milligrams/1.5 Milliliter Actuation, 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 or Agency) has determined that AXIRON (testosterone) transdermal metered solution, 30 milligrams (mg)/1.5 milliliter (mL) actuation, was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product if they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, is the subject of NDA 022504, held by Eli Lilly and Company and initially approved on November 23, 2010. AXIRON is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

In a letter dated September 5, 2017, Eli Lilly and Company requested withdrawal of NDA 022504 for AXIRON (testosterone). Eli Lilly and Company later submitted a letter dated September 7, 2017 correcting a typographical error in the September 5, 2017 letter. In the **Federal Register** of June 21, 2018 (83 FR 28856), FDA announced that it was withdrawing approval of NDA 022504, effective July 23, 2018.

K&L Gates LLP submitted a citizen petition received by FDA on June 27,