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Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 10, 2018.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Determination That AXIRON (Testosterone) Transdermal Metered Solution, 30 Milligrams/1.5 Milliliter Actuation, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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,

2018 (Docket No. FDA–2018–P–2506), under 21 CFR 10.25 and 21 CFR 10.30, requesting that the Agency determine whether AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list AXIRON (testosterone) transdermal metered solution, 30 mg/1.5 mL actuation, 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs that refer to this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24604 Filed 11–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Scoping Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In accordance with the National Environmental Policy Act, the National Institutes of Health (NIH) is issuing this notice to advise the public that an environmental impact statement will be prepared for the Surgery, Radiology and Lab Medicine Building with associated Utility Vault and Patient Parking Garage project located on the National Institutes of Health, Bethesda Campus, Bethesda, Maryland.

DATES: The Scoping Meeting is planned for November 28, 2018, from 6 p.m.-9 p.m., with the formal presentation to begin at 7 p.m. Scoping comments must be postmarked no later than December 29, 2018, to ensure they are considered.

ADDRESSES: The Scoping Meeting will be held at 6001 Executive Boulevard, Rockville, MD 20852. All comments and questions on the Scoping Meeting and the Environmental Impact Statement should be directed to Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email: *nihnepa@mail.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Deputy Director, Division of Environmental Protection, Office of Research Facilities, NIH, B13/2S11, 9000 Rockville Pike, Bethesda, Maryland 20892, telephone 301–496–7775; fax 301–480–0204; or email: *nihnepa@mail.nih.gov.* For the purpose of National Institutes of Health (NIH) and its National Environmental Policy Act (NEPA) procedures, the delegation of authority to administer, interpret and oversee the applicable environmental laws, Executive Orders and regulations for the NIH including the authority to oversee and manage the NIH NEPA program for assessing environmental impacts and publish final decisions has been given to the Director, Office of Research Facilities Development and Operation, Mr. Daniel G. Wheeland.

SUPPLEMENTARY INFORMATION: The NIH's mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability. In order to fulfill and uphold this mission the infrastructure of the NIH Bethesda Campus must be able to support the NIH's biomedical research programs.

The proposed Surgery, Radiology and Lab Medicine Building with associated Utility Vault and Patient Parking Garage project is to house General Radiology and Imaging Services (RADIS), the Department of Perioperative Medicine (DPM), the Department of Laboratory Medicine (DLM) and the relocated functions for the National Cancer Institute (NCI) in a state-of-the-art, safe, functionally efficient, flexible and cost-effective facility. During the study period, NIH expanded the building program to also include space for the National Heart, Lung & Blood Institute's (NHLBI) Cardiovascular Intervention Program (Cath Lab) and for the Interventional Radiology (IR) Program.

The proposed project consists of nine (9) levels above grade (including interstitial floors and a roof penthouse) and two (2) levels below grade. The proposed 505,200 building gross square feet (BGSF) of new construction will be linked to the west lab wing of the existing CRC (Building 10), which will include an additional 82,960 BGSF of interior renovation. The proposed new building addition foot print of 53,270 BGSF will be positioned between the CRC and Convent Drive.

The proposed project scope also includes the relocation of a portion of the existing campus utility tunnel, reconstruction of the displaced children's playground and connection to the new Pedestrian Tunnel that will be constructed with the proposed Patient Parking Garage across Convent Drive. Additionally, the project will include the installation of supporting infrastructure, such as emergency generators and medical gas storage, in the new Utility Vault and Utility Yard that will be constructed across Convent Drive as part of a separate, enabling project.

In accordance with 40 CFR 1500–1508 and Health and Human Services (HHS) environmental procedures, NIH will prepare an Environmental Impact Statement (EIS) for the proposed project. The EIS will evaluate the impacts of the alternatives should development occur as proposed. Among the items the EIS will examine are the implications of the project on community infrastructure, including, but not limited to, utilities, storm water management, traffic and transportation, and other public services.

To ensure that the public is afforded the greatest opportunity to participate in