Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–1215 for ''Post-Marketing Pediatric-Focused Product Safety Reviews; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Odegaard, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5151, Silver Spring, MD 20993, 301–796–8627, *amy.odegaard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA has established a public docket, Docket No. FDA–2019–N–1215, to receive input on post-marketing pediatric-focused safety reviews of products posted between October 12, 2018, and April 1, 2019, available on FDA's website at *https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm* but not presented at the April 8, 2019, PAC meeting. FDA welcomes comments by members of the PAC, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155), interested parties (such as academic researchers, regulated industries, consortia, and patient groups), and the general public. The docket number is FDA–2019–N–1215. The docket will open on April 2, 2019, and remain open until April 15, 2019. The post-marketing pediatric-focused safety reviews are for the following products from the following centers at FDA:

Center for Biologics Evaluation and Research

1. ADYNOVATE (Antihemophilic Factor [recombinant])
2. IXINITY (Coagulation Factor IX [Recombinant])
3. EPICEL (cultured epidermal autografts) (Humanitarian Device Exemption [HDE])

Center for Drug Evaluation and Research

1. ACZONE GEL (dapsone)
2. AIRDUO RESPICLICK (fluticasone propionate and salmeterol) and ARMONAIR RESPICLICK (fluticasone propionate)
3. AVELOX (moxifloxacin hydrochloride)
4. CALDOLOR INJECTION (ibuprofen)
5. CUBICIN INJECTION (daptomycin)
6. DEXILANT (dexlansoprazole)
7. EUCRISA OINTMENT (crisaborole)
8. LILETTA (levonorgestrel-releasing intrauterine system)
9. LYRICA (pregabalin)
10. NARCAN NASAL SPRAY (naloxone hydrochloride)
11. OFIRMEV (acetaminophen)
12. SELZENTRY (maraviroc)
13. SPIRIVA RESPIMAT (tiotropium bromide)
14. SYMBICORT INHALATION AEROSOL (budesonide/formoterol fumarate dehydrate)
15. TARCEVA (erlotinib hydrochloride)
16. VELCADE (bortezomib)

Center for Devices and Radiological Health

1. FLOURISH™ PEDIATRIC ESOPHAGEAL ATRESIA DEVICE (HDE)
2. LIPOSORBER LA–15 SYSTEM (HDE)
3. MEDTRONIC ACTIVA DYSTONIA THERAPY (HDE)

Dated: March 28, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06385 Filed 4–1–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0179]

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or the Agency) Center for Drug Evaluation and Research (CDER) is announcing the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). The purpose of this document is to invite pharmaceutical companies interested in participating in this program to contact CDER.

DATES: Pharmaceutical companies may send proposed agendas to the Agency by June 3, 2019.

FOR FURTHER INFORMATION CONTACT: Dan Brum, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5480, Silver Spring, MD 20993–0002, 301–796–0578, *dan.brum@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing its training program to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide the following: (1) Firsthand exposure to industry's drug development processes and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

II. The Site Tours Program

In this program, over a 2- to 3-day period, small groups (five or less) of CDER regulatory project managers, including a senior level regulatory project manager, can observe operations of pharmaceutical manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to improve mutual understanding and to provide an avenue for open dialogue. During the Site Tours Program, regulatory project managers will also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both CDER staff and industry. The primary objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, tracking mechanisms, and regulatory submission operations. The overall benefit to regulatory project managers will be exposure to project management, team techniques, and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Site Tours Program will be the responsibility of CDER; therefore, selection will be based on the availability of funds and resources for each fiscal year. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective regions. Firms that want to learn more about this training opportunity or that are interested in offering a site tour should respond by sending a proposed agenda by email directly to Dan Brum (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: March 27, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–06327 Filed 4–1–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–3691]

Determination That CHLOR–TRIMETON ALLERGY 12 HOUR (Chlorpheniramine Maleate) Extended Release Tablets, 8 Milligrams and 12 Milligrams, Were 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 CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 milligrams (mg) and 12 mg, were 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 as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Katelyn Mineo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–1054.

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.

CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg and 12 mg, are the subject of NDA 007638, held by Bayer HealthCare LLC (Bayer) and initially approved on August 15, 1950. CHLOR–TRIMETON ALLERGY 12 HOUR is indicated for temporary relief of the following symptoms due to hay fever or other upper respiratory allergies: sneezing; runny nose; itchy, watery eyes; itching of the nose or throat.

In the 2005 NDA 007638 Annual Report received on October 14, 2005, Bayer notified FDA that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended release tablets, 8 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated February 8, 2018, Bayer notified FDA that CHLOR–TRIMETON ALLERGY 12 HOUR (chlorpheniramine maleate) extended