Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 301–796–1697, *NewDrugCMC@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Naming of Drug Products Containing Salt Drug Substances.'' This draft guidance is being published to explain how CDER is implementing the U.S.P.'s policy entitled ''Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations.'' It is a naming and labeling policy applicable to drug products that contain an active ingredient that is a salt. The policy stipulates that U.S.P. will use the name of the active moiety, instead of the name of the salt when creating a drug product monograph title, and the strength will be expressed in terms of the active moiety. The policy allows for exceptions under specified circumstances. CDER is now applying this policy to new prescription drug products under development under section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355). FDA is separately considering applying the U.S.P. Salt Policy to nonprescription drug products, and to biological products licensed under the Public Health Service Act.

The U.S.P. Salt Policy became official on May 1, 2013, and U.S.P. is now applying it to all new drug product monographs for products that contain an active ingredient that is a salt. It affects the development of new drug products, because a U.S.P. monograph title for a new drug product, in most instances, serves as the nonproprietary, or ''established'' name of the related drug product (section 502(e)(3) of the FD&C Act (21 U.S.C. 352(e)(3)). If a drug product's label or labeling contains a name that is inconsistent with the applicable monograph title, it risks being misbranded (section 502(e)(1)(A)(i) of the FD&C Act).

This draft guidance describes the U.S.P. policy and discusses how CDER and industry can implement the policy. Following the policy will help reduce medication errors caused by a mismatch between the established name and strength on the label of drug products that contain a salt. More accurate naming of drug products containing a salt helps health care practitioners calculate equivalent doses when changing from one dosage form to another.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent CDER's current thinking on drug product naming nomenclature for new drugs that contain a salt as the active ingredient. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (the PRA) of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this draft guidance that are related to the burden for the submission of investigational new drug applications are covered under 21 CFR 312 and have been approved under OMB control number 0910–0014. The collections of information referenced in this draft guidance that are related to the burden for the submission of new drug applications are covered under 21 CFR 314 have been approved under OMB control number 0910–0001. The submission of prescription drug product labeling under 21 CFR 201.56 and 201.57 is approved under OMB control number 0910–0572.

In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: December 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30800 Filed 12–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1618]

Draft Prescription Drug User Fee Act V Information Technology Plan; Availability for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for public comment of the draft information technology (IT) plan entitled ''PDUFA V Information Technology Plan.'' This plan is intended to provide FDA's approach for enhancing business processes, data quality and consistency, supporting technologies, and IT operations as described in the Prescription Drug User Fee Act (PDUFA) Reauthorization Performance Goals and Procedures for Fiscal Years 2013 through 2017. FDA is publishing a draft version of the IT plan for comment to allow industry and other interested stakeholders to provide feedback as FDA moves towards a fully automated standards-based environment that enhances the regulatory review process for human pharmaceuticals.

DATES: Submit either electronic or written comments by February 24, 2014.

ADDRESSES: Submit written requests for single copies of the draft ''PDUFA V Information Technology Plan'' to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your

requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft plan.

Submit electronic comments on the draft plan to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cheryl Ford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6737, *UserFeesProgram-Informatics@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The draft PDUFA V IT plan considers assumptions, available resources, and statutory requirements that conform to the Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012. Section 1136 of FDASIA, Electronic Submission of Applications, gives FDA the authority to require a standardized electronic format for the submission of information and data in standardized formats. Section 1136 addresses investigational new drug applications, biologics license applications, and new drug applications under the PDUFA program as well as abbreviated new drug applications under the Generic Drug User Fee Act program and describes new standards and processes affecting drug and biologics approvals, drug supply chain, and other topics related to human pharmaceuticals. The draft PDUFA V IT plan describes key activities for enabling progress toward achieving PDUFA IT goals.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/ForIndustry/UserFees/default.htm* or *http://www.regulations.gov.*

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30818 Filed 12–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Allergenic Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Allergenic Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 28, 2014, between approximately 8:30 a.m. and 3:30 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be Web cast. The link for the Web cast is available at: *https://collaboration.fda.gov/apac.*

Contact Person: Gail Dapolito or Joanne Lipkind, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On January 28, 2014, the committee will meet in open session to discuss and make recommendations on the safety and efficacy of RAGWITEK, a short ragweed pollen allergen extract tablet for sublingual use, manufactured by Merck, indicated for immunotherapy for diagnosed ragweed pollen induced allergic rhinitis, with or without conjunctivitis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 21, 2014. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on January 28, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 13, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 14, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to