burden for this information collection is 37 hours.

Dated: December 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30804 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–1615]

Draft Generic Drug User Fee Act 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 ''GDUFA 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 Generic Drug User Fee Act (GDUFA) 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 ''GDUFA 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

Signed into law on July 9, 2012, GDUFA is designed to speed the delivery of safe and effective generic drugs to the public. GDUFA increases FDA's authorities and responsibilities to address issues such as drug shortages, drug supply chain, safety, security, and drug innovation. As generic drugs account for more than three-quarters of all prescriptions dispensed in the United States, GDUFA authorizes FDA to collect user fees from industry that will provide funding to expand and modernize FDA's generic drug regulatory process.

The draft GDUFA 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 abbreviated new drug applications under the GDUFA program as well as investigational new drug applications, biologics license applications, and new drug applications under the Prescription 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 GDUFA IT plan describes key activities for enabling progress toward achieving GDUFA 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. 2013–31008 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–D–1566]

Draft Guidance for Industry on Naming of Drug Products Containing Salt Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Naming of Drug Products Containing Salt Drug Substances.'' The United States Pharmacopeial (U.S.P.) Convention has adopted a monograph naming policy that changed the nomenclature for compendial drug products that contain a salt. Under the new policy, drug names and strengths for new compendial drug products will be based on the active moiety. The name and strength of the active ingredient (e.g., salt) will appear elsewhere on the drug product label and labeling. The policy became official on May 1, 2013. This draft guidance describes the U.S.P. policy, discusses the Center for Drug Evaluation and Research's (CDER's) application of the policy, and recommends how CDER and industry can implement the policy.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 26, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 guidance document.

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