comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–27306 Filed 12–18–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6716]

New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products.'' The purposes of the workshop are to present the outcomes from the research projects conducted under the Generic Drug User Fee Amendments (GDUFA) Regulatory Science Research Program; discuss how regulatory science initiatives have helped address regulatory science knowledge gaps by providing insights on factors that influence the performance of generic orally inhaled and nasal drug products (OINDPs); share the Agency's experience on the utility of novel analytical tools and methods developed under the regulatory science initiative for generic OINDP product development and bioequivalence assessments; and obtain input from the public on what, when, where, and how analytical methods and procedures should be applied in the development and review of abbreviated new drug applications (ANDAs) for complex OINDPs.

DATES: The public workshop will be held on January 9, 2018, from 8:30 a.m. to 4:30 p.m. Individuals who wish to attend the workshop must register by December 30, 2017. Submit either electronic or written comments on this public workshop by February 14, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503 B+C), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 14, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 14, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets 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–2017–N–6716 for ''New Insights for Product Development and Bioequivalence Assessments of Generic Orally Inhaled and Nasal Drug Products.'' 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.'' The Agency 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: Renishkumar Delvadia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4704, Silver Spring, MD 20993, 240–402–7979, email: *Renishkumar.delvadia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the Regulatory Science Enhancements section of the GDUFA Reauthorization Performance Goals and Program Enhancement Fiscal Years 2018–2022 (GDUFA II Commitment Letter) (available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM525234.pdf*) FDA committed to ''conduct internal and external research to support fulfilment of submission review and pre-ANDA commitments.'' This continues commitments made in the GDUFA Program Performance Goals and Procedures for fiscal years 2013 through 2017 (GDUFA I Commitment Letter) (available at: *https://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf*). For complex OINDPs, this research is intended to support the development of scientific guidance and Agency policy to clarify the ANDA pathway for OINDPs and aid our understanding about the critical product attributes relevant for in vivo performance of OINDPs. This work has led to the development of tools beneficial to both industry and FDA for developing and evaluating generic OINDPs. This regulatory science research includes, but is not limited to, the following: (1) Identification of critical formulation and device attributes of generic OINDPs; (2) development of clinically relevant in vitro tools for prediction of in vivo regional drug deposition and dissolution from OINDPs; (3) development of computational fluid dynamic (CFD) and physiologically-based pharmacokinetic (PBPK) models for prediction of the local and systemic exposure of drugs delivered through OINDPs and to assess their applicability in generic OINDP development programs; and (4) identification, validation, and standardization of novel techniques that can be used for future bioequivalence assessments for generic OINDPs.

Since its commencement in 2012, the GDUFA Regulatory Science Research Program has continuously aided our understanding about the critical product attributes that are relevant for in vivo performance of OINDPs, and has led to the development of tools beneficial to both industry and FDA for developing and assessing generic OINDPs. Several external and internal research projects have been initiated under the GDUFA Regulatory Science Research Program. The outcomes from these research studies have provided valuable insight about the factors influencing the performance of OINDPs and have helped the Agency fill regulatory science gaps in this area. For instance, advanced modeling tools developed under this initiative, such as CFD and PBPK, can provide insights about patient-device interactions and information about both local and systemic bioavailability, which can better characterize critical device and formulation attributes to further our understanding of generic drug-device combination products. Clinically relevant mouth-throat and nasal models are another example of this research which have shown good in vivo correlations in predicting regional drug deposition; these physical models allow us to predict the impact of certain performance characteristics of OINDPs on regional drug deposition in a realistic manner, potentially without the need for conducting comparative clinical endpoint studies. Similarly, Morphologically Directed Raman Spectroscopy (MDRS), a novel particle sizing method explored under the initiative, has shown promise in differentiating nasal suspension formulations of different drug particle sizes, and has opened the possibility of a new regulatory pathway for the approval of generic nasal suspension products without the need to conduct a comparative clinical endpoint study. Another research outcome developed under the science initiative for OINDPs has been work involving in-vitro dissolution methods, which are providing insights on the bridge between local drug deposition and its downstream systemic bioavailability. Our enhanced understanding about OINDPs from these regulatory science-based initiatives have informed us during the development of product-specific guidances for OINDPs, resulting in the publication of more than 39 product-specific guidance documents since the implementation of GDUFA in 2012.

To enhance communication of recent advances, including those supported by GDUFA funds, FDA plans to hold a public workshop on new analytical methods and assessment criteria for characterization of OINDPs.

II. Purpose and Scope of the Workshop

The purposes of the workshop are as follows:

1. To present the outcomes from the research projects initiated under the GDUFA Regulatory Science Research Program;
2. To discuss how regulatory science initiatives have helped address regulatory science gaps by providing insight on factors that influence the performance of OINDPs;
3. To share the Agency's experience on the utility of novel analytical tools and methods developed under the regulatory science initiative for OINDP product development and bioequivalence assessments; and
4. To obtain input from the public on what, when, where, and how analytical methods and procedures should be applied in the development and review of complex OINDP ANDAs for therapeutic equivalence.

The scope of the workshop covers the current status of methods for characterization and bioequivalence evaluation of generic OINDPs.

The focus of this public workshop is on the evaluation of these new methods for characterizing and demonstrating therapeutic equivalence of OINDPs, including discussing the areas in which these methods may significantly contribute to generic product development and regulatory understanding, how and under what conditions the methods should be conducted and evaluated, and inherent scientific challenges with this complex class of products.

Public input will improve FDA's current understanding of present and future methods available for evaluating OINDP therapeutic equivalence. The knowledge gained through this workshop discussion will be summarized and disseminated to the scientific community by publication(s).

III. Scope of Public Input Requested

FDA seeks input from the public on when, where, and how to utilize new methods for development of generic OINDPs and in the regulatory review of bioequivalence. Specific topics to be addressed include:

1. Identifying the areas in which new in vitro and computational methods can contribute to the development of generic OINDPs;
2. Discussing how in vitro testing for demonstrating OINDP therapeutic equivalence should be conducted and evaluated; and
3. Addressing the scientific challenges in assessing critical quality attributes of OINDPs and in developing new

methods for demonstrating OINDP therapeutic equivalence.

Registration: Persons interested in attending this public workshop must register online by December 30, 2017, by going to *https://www.fda.gov/Drugs/NewsEvents/ucm576064.htm.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. The workshop agenda and other background materials will be available approximately 2 weeks before the workshop at *https://www.fda.gov/Drugs/NewsEvents/ucm576064.htm.* The agenda will include time for questions and answers throughout the day and for general comments and questions from the audience following panel discussions.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by December 30, 2017, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:30 a.m.

If you need special accommodations due to a disability, please contact Renishkumar Delvadia no later than December 30, 2017.

Streaming Webcast of the public workshop: This public workshop will also be webcast. A live webcast of this workshop will be viewable at *https://collaboration.fda.gov/r19djs3yfsf/* on the day of the workshop. A video record of the workshop will be available at the same web address for 1 year. If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: December 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27279 Filed 12–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0075]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 18, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0119. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Good Laboratory Practice Regulations for Nonclinical Studies—21 CFR Part 58

OMB Control Number 0910–0119—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360b, and 360e) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the Agency issued good laboratory practice (GLP) regulations for nonclinical laboratory studies in part 58 (21 CFR part 58). The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a safety study, records and reports, and laboratory disqualification.

Part 58 requires testing facilities engaged in conducting toxicological studies to retain, and make available to regulatory officials, records regarding compliance with GLPs. Records are maintained on file at each testing facility and examined there periodically by FDA inspectors. The GLP regulations require that, for each nonclinical laboratory study, a final report be prepared that documents the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also require written records pertaining to: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses, and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

Recordkeeping is necessary to document the conduct of nonclinical laboratory studies of FDA-regulated products to ensure the quality and integrity of the resulting final study report on which a regulatory decision may be based. Written SOPs and records of actions taken are essential for testing facilities to implement GLPs effectively. Further, they are essential for FDA to be able to determine a testing facility's compliance with the GLP regulations in part 58.

In a notice of proposed rulemaking published in the **Federal Register** of August 24, 2016 (81 FR 58342), we proposed changes in our GLP regulations, including some of those listed in tables 1 and 2 of this document. The document included