DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4368]

Assessing the Effects of Food on Drugs in Investigational New Drug Applications and New Drug Applications—Clinical Pharmacology Considerations; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' This draft guidance provides recommendations to sponsors planning to conduct food-effect trials for orally administered products as part of investigational new drug applications (INDs), new drug applications (NDAs), and supplements to these applications. This draft guidance, when final, revises and replaces part of the 2002 FDA guidance for industry entitled ''Food-Effect Bioavailability and Fed Bioequivalence Studies'' (2002 Food Effect Guidance).

DATES: Submit either electronic or written comments on the draft guidance by April 29, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2018–D–4368 for ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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.

FOR FURTHER INFORMATION CONTACT: Vikram Arya or Brian Booth, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1499 or 301–796–1508.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' Food-drug interactions can significantly impact patient outcomes by affecting the pharmacokinetics and pharmacodynamics of some drugs. These interactions can potentially lead to reduced drug absorption and decreased efficacy or increased drug absorption and increased efficacy. Food can also have either a positive or negative effect on the incidence and severity of adverse events associated with drug use. The timely conduct of well-designed food-effect studies is critical to optimize the safety and efficacy of the drug product. This draft guidance provides recommendations on the following items: (1) When and how to conduct food-effect studies; (2) how to report the study results; and (3) how to include appropriate language regarding administration of the drug with food in the labeling.

FDA is specifically seeking feedback on the following issues:

- Please comment on the definition of the meal content. Should meal types be defined solely by the calorie and fat content, or should carbohydrates and proteins also be included?
- Please comment on the definition of the low-fat meal. Are the 400–500 calories and 25 percent fat a sufficient definition of a low-fat meal (refer also to table 2)?
- Please comment on the Biopharmaceutics Classification System-based waiver for food-effect trials. Does current science support this biowaiver?

Information on fed bioequivalence (BE) studies to be submitted in abbreviated new drug applications (ANDAs) can be found in the FDA draft guidance for industry entitled ''Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' Specific recommendations concerning fed comparability trials are now found in the FDA draft guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' When finalized these guidances will represent the current thinking of FDA on these topics.

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 the current thinking of FDA on ''Assessing the Effects of Food on Drugs in INDs and NDAs—Clinical Pharmacology Considerations.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 314 (21 CFR part 314), including §§ 314.50 and 314.94, have been approved under OMB control number 0910–0001. The collections of information in part 312 (21 CFR part 312), including § 312.23, have been approved under OMB control number 0910–0014. The collection of information in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572. The collections of information related to pharmacogenomic data have been approved under OMB control number 0910–0557.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: February 20, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–03247 Filed 2–25–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0143]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

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 March 28, 2019.

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 0910–0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Foreign Supplier Verification Programs (FSVP) for Food Importers

OMB Control Number 0910–0752—Extension

This information collection supports FDA regulations at 21 CFR part 1, subpart L—Foreign Supplier Verification Programs for Food Importers, as well as associated guidance. As amended by the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353), the Federal Food, Drug, and Cosmetic Act (FD&C Act) enables the Agency to better protect the public health by helping to ensure the safety and security of the food supply. The regulations are intended to help ensure that food imported into the United States is produced in compliance with specific processes and procedures, including reasonably appropriate risk-based preventive controls. The regulations establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances that a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions.

To assist respondents with understanding the regulatory requirements, we have developed Agency guidance, which is available at: *https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm.*

In the **Federal Register** of October 22, 2018 (83 FR 53271), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden for the information collection as follows: