

Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is proposing data collection as part of the study, "Survey of Youth Transitioning from Foster Care." This Notice provides the

opportunity to comment on a survey of youth with current or recent involvement in foster care.

Primary data collected includes a one-time survey with up to 780 youth aged 18 or 19 who were in foster care during their 17th year. The survey will be conducted in-person, with both field interviewer-administered items and Audio-Computer Assisted Self-Interview (ACASI) items that the youth will complete privately for sensitive topics. Survey questions will be focused on the youths' demographic data,

trafficking and other victimization histories, internal and external assets, and risk and protective factors. Involvement with child welfare and juvenile justice systems, and utilization of other services will also be addressed in the data collection.

Respondents: Youth aged 18 or 19 who were in foster care during their 17th year.

Annual Burden Estimates

Data collection is expected to take place over 2 years.

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Survey of Youth Transitioning from Foster Care	780	390	1	1.2	468

Estimated Total Annual Burden Hours: 468.

Authority: Section 476(a)(1–2) (42 U.S.C. 676) of the Social Security Act Part E—Federal Payments for Foster Care and Adoption Assistance.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–04805 Filed 3–9–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6084]

Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control." This draft guidance replaces the guidance for industry entitled "Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes" and the draft guidance for industry "Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention," both of which are being withdrawn. This draft guidance outlines the Agency's current recommendations on the evaluation of safety for new drugs and biologics to improve glycemic control in patients

with type 2 diabetes. Publication of this guidance is intended to provide clarity on the expectations for the development of drugs and biologics to improve glycemic control and to serve as a focus for commentary and feedback.

DATES: Submit either electronic or written comments on the draft guidance by June 8, 2020 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–2019–N–6084 for "Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control." 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.govinfo.gov/content/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:

Silvana Borges, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3200, Silver Spring, MD 20993–0002, 301–796–0963.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control.” This draft guidance replaces the guidance for industry entitled “Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes,” published in December 2008, and the draft guidance for industry “Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention,” published in February

2008, both of which are being withdrawn.

In response to questions and concerns about increased cardiovascular risk with certain antidiabetic therapies, FDA convened an advisory committee meeting in July 2008 to discuss the role of cardiovascular risk assessments for the safety evaluation of drugs and biologics developed for the treatment of type 2 diabetes. Based, in part, on comments expressed at that meeting, the Agency issued a guidance for industry in December 2008 outlining recommendations on the evaluation of cardiovascular risk for new antidiabetic therapies. That guidance stated that developers should demonstrate that new antidiabetic drugs and biologics would not result in an unacceptable increase in cardiovascular risk.

Since that time, FDA has reviewed the results of several cardiovascular outcome trials (CVOTs) conducted to meet the December 2008 guidance recommendations. None of the CVOTs to date have identified an increased risk of ischemic cardiovascular events; some of the CVOTs have instead demonstrated a reduced risk for cardiovascular events. In light of the CVOT results, FDA is revisiting the recommendations of the December 2008 guidance and is now proposing an updated approach to evaluating the safety of new drugs and biologics to improve glycemic control. In addition, FDA is withdrawing the February 2008 guidance because its recommendations for safety assessment have become outdated.

FDA is establishing this docket to solicit input from stakeholders on all aspects of these issues, including comments on specific questions posed in section II, Additional Issues for Consideration.

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 “Type 2 Diabetes Mellitus: Evaluating the Safety of New Drugs for Improving Glycemic Control.” 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.

II. Additional Issues for Consideration

FDA is soliciting comments from stakeholders regarding the issues described in this notice and the draft guidance. In addition to any other aspects of the guidance that stakeholders may care to comment upon, FDA is interested in answers to

the following questions/topics in particular:

A. Size of Population and Exposure to the Investigational Drug/Biologic

1. Is it more important to emphasize the number of patients exposed or the amount of exposure (*i.e.*, number of patient-years)? Or should there be expectations set for both parameters?

2. What would constitute a minimally acceptable database (either in number of patients, number of patient-years, or both) in terms of exposure to investigational drug/biologic at time of filing of the marketing application?

B. Demographic Characteristics of the Population

1. What are the important comorbid conditions to include?

2. What would be a minimally acceptable number of patients or number of patient-years to include for each important comorbid condition?

C. Necessary Safety Evaluations

1. Are there specific safety concerns for patients with type 2 diabetes that should be rigorously evaluated?

2. If there are specific safety concerns that should be rigorously evaluated, how should that assessment be conducted?

3. Is the adjudication of adverse events related to a specific safety concern a necessary part of the safety assessment? If so, should it be conducted by an independent, blinded adjudication committee or would other means of adjudication be adequate?

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014; the collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001; and the collection of information for clinical trial data monitoring committees has been approved under OMB control number 0910–0581.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: March 5, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-04877 Filed 3-9-20; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0008]

Advisory Committee; Gastrointestinal Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Gastrointestinal Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Gastrointestinal Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until March 3, 2022.

DATES: Authority for the Gastrointestinal Drugs Advisory Committee will expire on March 3, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Jay Fajiculay, Division of Advisory Committee and Consultant Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: GIDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3, FDA is announcing the renewal of the Gastrointestinal Drugs Advisory Committee (the Committee). The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of gastrointestinal

diseases and makes appropriate recommendations to the Commissioner.

Pursuant to its Charter, the Committee shall consist of a core of 11 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of gastroenterology, endocrinology, surgery, clinical pharmacology, physiology, pathology, liver function, motility, esophagitis, and statistics. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/gastrointestinal-drugs-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: March 4, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020-04778 Filed 3-9-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6644]

Fiscal Year 2020 Generic Drug Regulatory Science Initiatives; 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 “FY 2020 Generic Drug Regulatory Science Initiatives.” The purpose of the public workshop is to provide an overview of the status of regulatory science initiatives for generic drugs and an opportunity for public input on these initiatives. FDA is seeking this input from a variety of stakeholders—industry, academia, patient advocates, professional societies, and other interested parties—as it fulfills its commitment under the Generic Drug User Fee Amendments of 2017 (GDUFA II) to develop an annual list of regulatory science initiatives specific to generic drugs. FDA will take the information it obtains from the public workshop into account in developing its fiscal year (FY) 2021 regulatory science initiatives.

DATES: The public workshop will be held on May 4, 2020, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by June 4, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503, sections B and C), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Bldg. 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 June 4, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 4, 2020. 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,