FDA to use qualitative social/behavioral science data collection techniques (*i.e.,* individual indepth interviews, small group discussions, focus groups, and observations) to better understand stakeholders' perceptions, attitudes, motivations, and behaviors regarding various issues associated with food and cosmetic products, dietary supplements, and animal food and feed. Understanding these consumers', manufacturers', and producers' perceptions, attitudes, motivations, and behaviors plays an important role in improving FDA's communications that impact these various stakeholders and assists in the development of quantitative study proposals, complementing other important research efforts in the Agency.

To obtain approval for an individual generic submission collection that meets the conditions of this generic clearance, an abbreviated supporting statement will be submitted to OMB along with supporting documentation (*e.g.,* a copy of the interview or moderator guide, screening questionnaire).

Selection for potential respondents is done via a screening process to match the best possible respondent to each individual generic submission. Respondents to individual requests made under the generic clearance, once approved by OMB, may include a wide range of consumers and other FDA stakeholders, such as producers and manufacturers who are regulated under FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed. Participation is voluntary.

In the **Federal Register** of April 10, 2023 (88 FR 21193), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the four collection of information topics solicited and therefore will not be discussed.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual Indepth Interview Screening	4,800	1	4,800	0.08 (5 minutes)	384
Individual Indepth Interviews	400	1	400	1	400
Focus Group/Small Group Participant Screening	10,800	1	10,800	0.08 (5 minutes)	864
Focus Groups/Small Group Discussion	3,600	1	3,600	1.5	5,400
Observation Screening	720	1	720	0.08 (5 minutes)	58
Observations	144	1	144	2	288
Total			20,464		7,394

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Current estimates are based on both historical numbers of participants from past projects as well as estimates for projects to be conducted in the next 3 years. The collections we have conducted under this generic collection of information have informed and helped us better understand stakeholder perceptions, attitudes, motivations, and behaviors to help us improve our communications to them.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 2, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16924 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–2439]

QTc Information in Human Prescription Drug and Biological Product Labeling; 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 ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' This guidance is intended to assist applicants with incorporating corrected QT (QTc) interval prolongation-related information into the labeling of non-antiarrhythmic human prescription drug and biological products. The guidance provides recommendations on how and where to appropriately include the clinically relevant information on QTc interval prolongation in the labeling, in accordance with regulatory requirements for the content and format of human prescription drug labeling.

DATES: Submit either electronic or written comments on the draft guidance by October 10, 2023 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–2023–D–2439 for ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' 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, 240–402–7500.

• 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, 240–402–7500.

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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: William Pierce, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2159, Silver Spring, MD 20993, 301–796–0521; or Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' This guidance is intended to assist applicants with incorporating corrected QT (QTc) interval prolongation-related information into the labeling of non-antiarrhythmic human prescription drug and biological products. An undesirable property of some non-antiarrhythmic drugs is their ability to delay cardiac repolarization. A delay in cardiac repolarization creates an electrophysiological environment that favors the development of torsade de pointes (TdP), which can degenerate into ventricular fibrillation, leading to sudden death. While the degree of QT prolongation is recognized as an imperfect biomarker for proarrhythmic risk, in general, there is a qualitative relationship between QT prolongation and the risk of TdP, especially for drugs that cause prolongation of the QT interval due to inhibition of the delayed rectifier potassium channel.

FDA and the International Council for Harmonisation recommend that applicants for most non-antiarrhythmic drugs with systemic bioavailability assess effect on cardiac repolarization early in clinical development including a clinical electrocardiographic evaluation. The QTc assessment in early clinical development may inform the intensity and continuation of electrocardiogram (ECG) monitoring in late phase clinical trials. A finding of QTc interval prolongation in early clinical development may support continuing ECG monitoring in subsequent clinical trials. The guidance provides recommendations and examples on how and where to appropriately include the clinically relevant information on QTc interval prolongation in labeling, in accordance with regulatory requirements for the content and format of human prescription drug labeling.

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 ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' 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. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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 collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections

of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16930 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIEHS Videocast at the following link: *https://www.niehs.nih.gov/news/webcasts/index.cfm.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: September 12–13, 2023.

Open: September 12, 2023, 9:00 a.m. to 9:15 a.m.

Agenda: Call to Order and Opening Remarks, Review of Confidentiality and Conflict of Interest, and Consideration of June 2023 Meeting Minutes.

Open: September 12, 2023, 9:15 a.m. to 10:00 a.m.

Agenda: All of Us.

Open: September 12, 2023, 10:00 a.m. to 10:45 a.m.

Agenda: AI, NAM and Toxicology.

Open: September 12, 2023, 10:45 a.m. to 11:30 a.m.

Agenda: AI and multi-omic integration.

Open: September 12, 2023, 12:30 p.m. to 1:15 p.m.

Agenda: AI and the Exposome.

Open: September 12, 2023, 1:15 p.m. to 2:00 p.m.

Agenda: Ethical AI.

Open: September 12, 2023, 2:00 p.m. to 2:45 p.m.

Agenda: DTT Speaker ToxPipe: Semi-Autonomous AI Integration of Diverse Toxicological Data Streams.

Open: September 12, 2023, 2:45 p.m. to 3:45 p.m.

Agenda: Council Discussion.

Closed: September 12, 2023, 4:00 p.m. to 4:15 p.m.

Agenda: To review and evaluate review of Confidentiality and Conflict of Interest.

Closed: September 12, 2023, 4:15 p.m. to 5:00 p.m.

Agenda: To review and evaluate consideration of Grant Applications.

Date: September 13, 2023.

Open: September 13, 2023, 9:00 a.m. to 10:00 a.m.

Agenda: Report of the NIEHS Director.

Open: September 13, 2023, 10:00 a.m. to 10:45 a.m.

Agenda: Report of the DERT Director.

Open: September 13, 2023, 10:45 a.m. to 11:15 a.m.

Agenda: Report on Multi-Omics Program with HG.

Open: September 13, 2023, 11:15 a.m. to 12:00 p.m.

Agenda: EPCOT Concept.

Open: September 13, 2023, 12:00 p.m. to 12:45 p.m.

Agenda: Worker Training Program Concept.

Place: NIEHS, Building 101, Rodbell Auditorium, Research Triangle Park, NC.

Contact Person: David M. Balshaw, BA, Ph.D., Acting Director and Chief, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–27, Research Triangle Park, NC 27709–2233, 984–287–3234, *balshaw@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.niehs.nih.gov/dert/c-agenda.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 2, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16854 Filed 8–7–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: September 8, 2023.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Room 3172, Bethesda, MD 20892, (301) 402–8837, *barbara.thomas@nih.gov.*