ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–OGM–SF–PPR–B	2,000	2	.33	1,320

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 2 CFR part 200.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–21789 Filed 12–2–25; 8:45 am]

BILLING CODE 4184–01–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; 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 guidance for industry entitled ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' This guidance is intended to assist applicants with incorporating heart rate-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. This guidance finalizes the draft guidance of the same title issued on August 8, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on December 3, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Laleh Amiri-Kordestani, Oncology Center of Excellence and Center for Drug Evaluation and Research, Food and Drug Administration, *OCE-Guidances@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''QTc Information in Human Prescription Drug and Biological Product Labeling.'' This guidance is intended to assist applicants with incorporating heart rate-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 progress to ventricular fibrillation, leading to sudden death. While the degree of QTc interval prolongation is recognized as an imperfect biomarker for proarrhythmic risk, in general, there is a qualitative relationship between QTc interval prolongation and the risk of TdP, especially for drugs that cause prolongation of the QTc 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 frequency and continuation of electrocardiogram monitoring in late phase 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 guidance finalizes the draft guidance entitled, ''QTc Information in Human Prescription Drug and Biological Product Labeling,'' issued on August 8, 2023 (88 FR 53501). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft guidance to the final guidance include adding a section providing recommendations for including QTc interval prolongation information in FDA-approved patient labeling and a section for updating QTc interval prolongation information in currently-approved labeling. In addition, minor revisions and editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents 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 (PRA) (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 208 have been approved under OMB control number 0910–0393; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; 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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–21798 Filed 12–2–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–4634]

Monoclonal Antibodies: Streamlined Nonclinical Safety Studies; 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 ''Monoclonal Antibodies: Streamlined Nonclinical Safety Studies.'' The draft guidance provides recommendations for streamlined approaches to assess long-term safety from monoclonal antibodies that recognize a single molecular target (referred to as monospecific antibodies); describes when general toxicology studies are not warranted or may be limited to a short-term study; and addresses reproductive, developmental, and juvenile toxicity assessments. When finalized, the guidance is intended to assist sponsors in avoiding unnecessary use of animals, particularly non-human primates (NHPs), in furtherance of the 3R principles of reducing, refining, and replacing the use of animal testing.

DATES: Submit either electronic or written comments on the draft guidance by February 2, 2026 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