numbers 0910–0308 and 0910–0291 (Form FDA 3500A); the collections of information in part 601 have been approved under OMB control number 0910–0338; the collections of information in FDA's guidance entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control number 0910–0581; and, the collections of information in FDA's guidance entitled ''Emergency Use Authorization of Medical Products and Related Authorities'' have been approved under OMB control number 0910–0595.

III. Emergency Use Authorization for Vaccines To Prevent COVID–19 Guidance

In October 2020, FDA first issued a guidance entitled ''Emergency Use Authorization for Vaccines to Prevent COVID–19'' (Vaccine EUA guidance) to provide sponsors of requests for emergency use authorization (EUA) for COVID–19 vaccines with recommendations regarding the data and information needed to support the issuance of an EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb–3) for an investigational vaccine to prevent COVID–19. Although, the guidance stated that it was intended to remain in effect only for the duration of the public health emergency related to COVID–19 declared under the Public Health Service Act, in the **Federal Register** of March 13, 2023 (88 FR 15417 at 15421), FDA listed the guidance as one of the COVID–19-related guidances the Agency was revising to continue in effect for 180 days after the COVID–19 public health emergency declared under the PHS Act expired on May 11, 2023, during which time FDA planned to further revise those guidances. However, circumstances have changed since the end of the declared public health emergency on May 11, 2023. FDA has reviewed the Vaccine EUA guidance and determined that the guidance is no longer needed, as the Agency has shifted its focus toward communicating directly with individual manufacturers. Accordingly, the EUA guidance will no longer be in effect after the publication of the guidance for immediate implementation announced in this notice, ''Development and Licensure of Vaccines to Prevent COVID–19.''

IV. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: October 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23162 Filed 10–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–2316]

Benefit-Risk Assessment for New Drug and Biological Products; 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 final guidance for industry entitled ''Benefit-Risk Assessment for Human Drug and Biological Products.'' FDA has developed this guidance document in accordance with goals associated with the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) under Title I of the FDA Reauthorization Act of 2017 and requirements under the 21st Century Cures Act. The intent of this guidance is to provide drug sponsors and other stakeholders with better clarity on how considerations about a drug's benefits, risks, and risk management options factor into FDA's pre- and postmarket regulatory decisions about new drug applications (NDAs) or biologics license applications (BLAs). This guidance finalizes the draft guidance of the same title issued in September 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on October 20, 2023.

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–2020–D–2316 for ''Benefit-Risk Assessment for New Drug and Biological Products.'' 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 (CDER), 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5003, *Graham.Thompson@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Benefit-Risk Assessment for Human Drug and Biological Products.'' This guidance articulates the key considerations that factor into CDER's and CBER's benefit-risk assessments, including how patient experience data may be used to inform benefit-risk assessment. It discusses how sponsors, through their decisions and activities throughout the drug lifecycle, can inform FDA's benefit-risk assessment, as well as opportunities for interaction between FDA and sponsors to discuss benefit-risk considerations. It also discusses unique considerations for benefit-risk assessments that inform regulatory decision-making that occurs in the postmarket setting.

Industry stakeholders have indicated having a clearer understanding of FDA's decision-making context and benefit-risk considerations can help inform sponsors' decisions about their drug development programs and the evidence they generate in support of their NDA or BLA. Patients and other stakeholders may gain further insight into the key issues that inform FDA's assessment of benefit and risk, and a clearer understanding of how these issues fit into the regulatory framework of drug development and evaluation.

This guidance finalizes the draft guidance entitled ''Benefit-Risk Assessment for New Drug and Biological Products'' issued on September 30, 2021 (86 FR 54211). FDA considered comments received on the draft guidance in developing the final guidance. Changes from the draft to the final guidance include clarifying language on FDA's approach to benefit-risk assessment of new drugs and biologics, clarifying language on important considerations for FDA's premarket benefit-risk assessment of drugs and biologics, clarifying language on activities that occur in premarket development that inform benefit-risk assessment, and other editorial changes.

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 ''Benefit-Risk Assessment for New Drug and Biological Products.'' 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 part 314 have been approved under OMB control number 0910–0001 as follows: (1) the content and format of investigational new drugs applications, (2) expanded access uses and treatment of patients with immediately life-threatening conditions or serious diseases or conditions, (3) regulatory requirements pertaining to postmarketing study commitments, and (4) risk evaluation and mitigation strategies pertaining to benefit-risk assessments. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 as follows: (1) the content and format of NDAs, (2) the submission of the patient population, (3) the submission of clinical trial data, and (4) benefit-risk planning, including early consultations with FDA meetings in end-of-phase 2 and pre-NDA meetings. The collections of information for good laboratory practices for nonclinical laboratory studies have been approved under OMB control number 0910–0119. The collections of information for the submission of postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765. The collections of information in the guidance for industry entitled ''Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format (Periodic Benefit-Risk Evaluation Report)'' have been approved under OMB control number 0910–0230.

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: October 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23161 Filed 10–19–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: CAREWare Customer Satisfaction and Usage Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than December 19, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: CAREWare Customer Satisfaction and Usage Survey, OMB No. 0906–xxxx–New.

Abstract: HRSA developed CAREWare, a software application first released in 2000, to help meet the data collection and reporting needs of Ryan White HIV/AIDS Program (RWHAP) grant recipients. The secure software is a free, electronic health and social support services information system for RWHAP grant recipients and their subrecipients to assist in the data requirement submissions that inform the development of the Ryan White HIV/AIDS Program Service Report, the AIDS Drug Assistance Program Data Report, the Ending the HIV Epidemic Initiative Triannual Report, and the voluntary Clinical Quality Measures Performance Measures. Over time, the software has evolved into a comprehensive health information system and is now the source of more than half of all the RWHAP client-level data received from recipients and subrecipients of RWHAP grant funding. CAREWare software manages HIV clinical and support service data from more than 360,000 client records in 48 states; Washington, DC; Puerto Rico; and the U.S. Virgin Islands.

The CAREWare software application contains customizable modules for tracking demographic information, services, medications, laboratory test results, immunization history, diagnoses (updated with International Classification of Diseases, Tenth Revision codes), referrals to outside agencies, and an appointment scheduler. There is a custom report generator and a performance measures module that supports quality of care initiatives at the provider level. The software also has several ways to import data from third-party sources, including commercial labs and other electronic health records (using both Health Level Seven and simple Comma Separated Value-formatted files), HIV surveillance systems, and for RWHAP Part B AIDS Drug Assistance Programs, pharmacy benefit programs. The software and user support materials can be accessed here: *https://hab.hrsa.gov/program-grants-management/careware.* Finally, CAREWare supports users through an experienced helpdesk with ongoing software maintenance issues and enhancements to the user interface.

HRSA is proposing a customer satisfaction survey to gather feedback from CAREWare users regarding their experiences and satisfaction with the software platform and to obtain suggestions for improvement.

Need and Proposed Use of the Information: HRSA aims to understand CAREWare users' needs and concerns by collecting information on current software features and inquiring about opportunities to improve the user experience and product features. The survey will address the software's functionality and how well it meets the data collection, reporting, and quality management needs of the CAREWare user. The feedback will enable HRSA to assess, benchmark, and improve customer satisfaction with RWHAP grant recipients.

Likely Respondents: RWHAP recipients and providers who use CAREWare to produce data files for the Ryan White HIV/AIDS Program Service Report, the AIDS Drug Assistance Program Data Report, the Ending the HIV Epidemic Initiative Triannual Report, and the voluntary Clinical Quality Measures performance measures module.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
CAREWare User Survey	1,160	1	1,160	2	2,320
Total	1,160	1	1,160	2	2,320