Serving as a common claim form, the CMS–1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (*e.g.,* TRICARE, RRB, and Medicaid). *Form Number:* CMS–1500 (OMB Control Number: 0938–1197); *Frequency:* Occasionally; *Affected Public:* Private Sector, Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 2,451,781; *Number of Responses:* 975,664,249; *Total Annual Hours:* 17,163,310. (For policy questions regarding this collection contact Charlene Parks at 410–786–8684.)

Dated: September 12, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–20041 Filed 9–14–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989; 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 ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' Forms FDA 3988, Transmittal of PMR/PMC Submissions for Drugs and Biologics, and FDA 3989, PMR/PMC Annual Status Report for Drugs and Biologics, are intended to facilitate submissions by drug and biological product application holders of complete and accurate information on postmarketing requirements (PMRs) and postmarketing commitments (PMCs) in a consistent format. These forms are expected to result in improved accuracy and timeliness of FDA's identification and review of those submissions containing information on PMRs and PMCs. This guidance covers the purpose of each form, when to use these forms, and how to submit these forms. The guidance also explains where applicants will be able to find the forms and instructions. This guidance finalizes the draft guidance of the same name issued on October 21, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 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 should include the Docket No. FDA–2018–N–3771 for ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' 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; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–6054; 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 ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' This guidance is intended for applicants that are required to report annually on the status of postmarketing studies and clinical trials for human drug and biological products under section 506B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356b) and its implementing regulations at §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70). The forms were developed, in part, in response to the recommendations from the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) regarding the need for comparable information across annual status reports (ASRs) on PMRs and PMCs, to eliminate manual data entry and to enhance FDA's ability to track PMRs and PMCs. These forms are expected to result in improved accuracy and timeliness of FDA's identification and review of those submissions containing information on PMRs and PMCs. The purpose of the guidance is to explain why Forms FDA 3988 and FDA 3989 were created, describe the contents of the forms, and explain how to submit the forms electronically. The guidance also explains where applicants will be able to find the forms and instructions for their completion. Forms FDA 3988 and FDA 3989 are available for use at FDA's Forms web page (*https://www.fda.gov/about-fda/reports-manuals-forms/forms*).

PMRs and PMCs are studies or clinical trials conducted by the applicant after FDA has approved a drug or biological product for marketing or licensing. These studies or clinical trials can be required under statute or regulation (PMRs) or agreed upon in writing by FDA and the applicant (PMCs). Section 130(a) of the Food and Drug Administration Modernization Act of 1997 amended the FD&C Act by adding section 506B of the FD&C Act. Under section 506B of the FD&C Act and its implementing regulations at §§ 314.81(b)(2)(vii) and 601.70, applicants must submit an ASR on PMRs and PMCs.[1] This report must address the progress of the PMR/PMC or the reasons for failing to conduct the requirement or commitment (section 506B(a) of the FD&C Act).

This guidance does not apply to postmarketing studies or clinical trials that are not subject to the reporting requirements of section 506B of the FD&C Act.[2] For example, the guidance does not apply to voluntary studies or clinical trials performed by an applicant or on an applicant's behalf that are neither required nor agreed upon in writing. This guidance also does not apply to PMCs related to chemistry, manufacturing, and controls or stability studies.

In a December 2015 report from the GAO entitled ''Drug Safety: FDA Expedites Many Applications, but Data for Postapproval Oversight Need Improvement,'' [3] the GAO recommended that FDA improve its data tracking to ensure the completeness, timeliness, and accuracy of information in its database on PMRs/PMCs. Additionally, in a July 2016 HHS OIG study entitled ''FDA is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist,'' [4] the HHS OIG noted that FDA continued to have problems with its data management system and work processes, thereby hindering its ability to track PMRs. OIG recommended that FDA provide standardized forms for ASRs, ensure that the forms are complete, and require applicants to submit the forms electronically.

Based in part on the recommendations from GAO and HHS OIG, FDA created Forms FDA 3988 and FDA 3989 to improve the collection, identification, and use of information regarding PMRs and PMCs. Form FDA 3988 was developed to accompany an applicant's PMR/PMC-related submissions (*e.g.,* draft protocols, final protocols, interim reports, final reports, and PMR/PMC-related correspondence), except the ASR on PMRs and PMCs. Form FDA 3988 allows applicants to identify, in a standardized format, the type of PMR/PMC-related submission the applicant is making (*e.g.,* draft protocol) and the PMR or PMC to which the submission applies. Form FDA 3989 was developed so that applicants may provide ASR information on their PMRs and PMCs in a standardized format. The purpose of these forms is to assist applicants in providing clearly identified PMR/PMC-related submissions and in meeting their annual reporting requirements under section 506B of the FD&C Act and §§ 314.81(b)(2)(vii) and 601.70.

Use of Forms FDA 3988 and 3989 is optional, but FDA encourages their use because the forms should facilitate FDA management and review of the applicant's submissions, as well as enhance the accuracy of data within FDA's electronic document archiving systems. FDA uses these archiving systems as a source from which to obtain data published annually in the **Federal Register** as required under section 506B(c) of the FD&C Act and to provide quarterly status updates of the PMR and PMC data on FDA's Postmarket Requirements and Commitments public web page (available at *https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm*). This guidance finalizes the draft guidance of the same name issued on October 21, 2020 (85 FR 66995). In addition to editorial changes for clarification, changes from the draft to the final included a minor change regarding what to enter into field 9.g. of Form FDA 2252 and the removal of the appendices to the guidance, which contained drafts of Forms FDA 3988 and 3989.

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 ''Annual Status

[1] FDA defines postmarketing studies or clinical trials for which ASRs must be submitted under section 506B of the FD&C Act as those concerning a human drug or biological product's clinical safety, clinical efficacy, clinical pharmacology, or nonclinical toxicology that are either required by FDA (PMRs) or that are committed to, in writing, (PMCs) either at the time of approval of an application or a supplement or after approval of an application or supplement. See §§ 314.81(b)(2)(vii) and 601.70. FDA interprets section 506B of the FD&C Act to apply to postmarketing studies and clinical trials that are required under section 505B of the FD&C Act (21 U.S.C. 355c), the animal efficacy rule (21 CFR 314.610(b)(1) and 601.91(b)(1)), accelerated approval (section 506(c)(2)(A) of the FD&C Act (21 U.S.C. 356(c)(2)(A)); 21 CFR 314.510 and 601.41), and the Food and Drug Administration Amendments Act of 2007 (section 505(*o*)(3) of the FD&C Act (21 U.S.C. 355(*o*)(3)).

[2] Under § 314.81(b)(2)(viii), applicants submitting an annual report for human drug products must include a status report of postmarketing studies and clinical trials not included under § 314.81(b)(2)(vii) that are being performed by, or on behalf of, the applicant.

[3] Available at *https://www.gao.gov/products/GAO-16-192.*

[4] Available at *https://oig.hhs.gov/oei/reports/oei-01-14-00390.asp.*

Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' 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 for applicants required to submit ASRs on PMCs and PMRs under section 506B of the FD&C Act and the implementing regulations at §§ 314.81(b)(2)(vii) and 601.70 are approved under OMB control numbers 0910–0001 and 0910–0338, respectively.

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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–20014 Filed 9–14–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5966]

Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff; 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 entitled ''Breakthrough Devices Program.'' This final guidance describes policies that FDA intends to use to implement a section of the Federal Food, Drug, and Cosmetic Act (FD&C Act). This guidance updates the previous version of the guidance, of the same title, issued on December 18, 2018, and describes how the Breakthrough Devices Program may also be applicable to certain devices that benefit populations impacted by health and/or healthcare disparities. Consistent with our obligations under the SUPPORT for Patients and Communities Act (SUPPORT Act), the Breakthrough Devices Program may be available for certain non-addictive medical products to treat pain or addiction.

DATES: The announcement of the guidance is published in the **Federal Register** on September 15, 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–2017–D–5966 for ''Breakthrough Devices Program.'' 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a