TABLE 5— CDER GUIDANCES AND COLLECTIONS—Continued

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB control No(s).	New collection covered by PHE PRA waiver
		Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program.		

C. CFSAN Guidance

The guidance indicated in the table below refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the table. This guidance also contains a new collection of information not approved under a current collection. This new collection of information has been granted a PHE waiver from the PRA by the HHS on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

TABLE 6—CFSAN GUIDANCE AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB control No(s).	New collection covered by PHE PRA waiver
Temporary Policy Regarding Certain Mandatory Food Labeling Requirements During the COVID–19 Public Health Emergency: Minor Formulation Changes and Vending Machines.	21 CFR part 101; section 403(w) of the FD&C Act.	.....	0910–0381, 0910–0782, 0910–0792.	Recommend that manufacturers post ingredient omissions or substitutions not reflected on the product label.

The guidance entitled ''Returning Refrigerated Transport Vehicles and Refrigerated Storage Units to Food Uses After Using Them to Preserve Human Remains During the COVID–19 Pandemic'' contains no collection of information. Therefore, clearance by OMB under the PRA is not required.

D. CVM Guidance

This guidance indicated in the table below refers to previously approved collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidance have been approved by OMB as indicated in the table. This guidance also contains a new collection of information not approved under a current collection. This new collection of information has been granted a PHE waiver from the PRA by HHS on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.*

TABLE 7—CVM GUIDANCE AND COLLECTION

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance referenced in COVID–19 guidance	OMB control No(s).	New collection covered by PHE PRA waiver
GFI# 271, Reporting and Mitigating Animal Drug Shortages during the COVID–19 Public Health Emergency.	21 CFR 514.1(a))	.....	0910–0032, 0910–0669	Reporting and mitigating animal drug shortages.

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- The FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;*
- the FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or
- *https://www.regulations.gov.*

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13829 Filed 6–25–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1459]

Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is hosting a virtual public meeting entitled ''Generic Drug User Fee

Amendments (GDUFA) of 2017.'' At the end of September 2022, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (*i.e.,* the GDUFA II Commitment Letter), provide a period of 30 days after the public meeting to obtain written comments from the public, and publish the comments on FDA's website. FDA invites public comment on the GDUFA program and suggestions regarding the features FDA should propose for the next GDUFA program cycle. These comments will be published and available on FDA's website.

DATES: The public meeting will be held on July 21, 2020, from 8:30 a.m. to 3:30 p.m., and will take place virtually and will be held by webcast only. Submit either electronic or written comments on this public meeting by August 20, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

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 August 20, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 20, 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, 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–N–1459 for ''Generic Drug User Fee Amendments; Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993, 301–796–2882, *Tiana.Barnes@fda.hhs.gov;* or Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926, *Dat.Doan@fda.hhs.gov;*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, which included GDUFA (Pub. L. 112–144, Title III), was signed into law by the President. In 2017, the GDUFA program was reauthorized (GDUFA II) under the FDA Reauthorization Act of 2017 (Pub. L. 115–52, Title III), which authorizes FDA to collect fees for certain generic human drug applications, drug master files, and facilities. Designed to speed access to safe and effective generic drugs to the public, GDUFA II requires that generic drug manufacturers and other relevant entities pay user fees to finance critical and measurable generic drug program enhancements. As described in the GDUFA II Commitment Letter, FDA committed to achieve certain performance goals, provide enhanced communication intended to streamline abbreviated new drug application (ANDA) development and assessment, and take other steps to increase the efficiency of the assessment process.

GDUFA II also includes a pre-ANDA program to clarify regulatory expectations for complex generic product developers early in product development and during application review.

Additional information concerning GDUFA, including the text of the law, the GDUFA II Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA website at *https://www.fda.gov/gdufa.*

II. Topics for Discussion at the Public Meeting

FDA is interested in responses to the following general questions:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?
- What new features should FDA consider adding to the program to enhance efficiency and effectiveness of the generic drug review process?

FDA welcomes any other relevant information the public would like to share as it relates to the GDUFA program, including but not limited to the following topic areas:

- supply chain security and drug shortages;
- drug quality and advanced manufacturing; and
- complex products.

In general, the public meeting's format will include presentations by FDA and our stakeholders, which may include scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. The amount of time available for public testimony will be determined by the number of persons who register to present during the virtual public meeting. A draft agenda and other background information for the public meeting will be posted at *https://www.fda.gov/gdufa* by July 14, 2020.

III. Participating in the Public Meeting

Registration: FDA is seeking participation (*i.e.,* oral remote presentations) during the virtual public meeting by all interested parties, including but not limited to scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. Persons interested in attending this virtual public meeting should register online by 11:59 p.m. Eastern Time on July 7, 2020, at *https://collaboration.fda.gov/e8a35s83so0x/event/registration.html.* Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Requests for Oral Presentations: If you wish to present during a public comment session or participate in a specific session, please submit your request to *GenericDrugPolicy@fda.hhs.gov* by 11:59 p.m. Eastern Time on July 7, 2020. Your email should contain which topic(s) you wish to address and include complete contact information, including name, title, affiliation, address, and email address. We will do our best to accommodate requests to make public comments and requests to participate in specific sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 8, 2020. All requests to make oral presentations must be received by the close of registration on July 7, 2020, 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to *GenericDrugPolicy@fda.hhs.gov* no later than July 14, 2020. No commercial or promotional material will be permitted to be presented or distributed during the virtual public meeting.

Streaming Webcast of the Public Meeting: This virtual public meeting will be accessible via webcast only. In order to connect to the webcast, you must have Adobe Connect. The link for the webcast will be sent to all registered attendees in advance of the event.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/gdufa.*

Dated: June 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–13749 Filed 6–25–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 27, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Membership Forms for Organ Procurement and Transplantation Network OMB No. 0915–0184–Revision.