TABLE 4—FEE SCHEDULE FOR FY 2020—Continued

Fee category	Fees rates for FY 2020
Facilities:	
Active Pharmaceutical Ingredient (API) Domestic	44,400
API—Foreign	59,400
Finished Dosage Form (FDF)—Domestic	195,662
FDF—Foreign	210,662
Contract Manufacturing Organization (CMO)—Domestic	65,221
CMO—Foreign	80,221
GDUFA Program:	
Large size operation generic drug applicant	1,661,684
Medium size operation generic drug applicant	664,674
Small business operation generic drug applicant	166,168

X. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2019. To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, a Generic Drug User Fee Cover Sheet must be completed, available at *https://www.fda.gov/gdufa* and *https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and a user fee identification (ID) number must be generated. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, credit card, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic Drug User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (Note: Only full payments are accepted; no partial payments can be made online.) Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

The user fee ID number must be included on the check, bank draft, or postal money order and must be made payable to the order of the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. For questions concerning courier delivery, U.S. Bank can be contacted at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be written on the check, bank draft, or postal money order.

For payments made by wire transfer, the unique user fee ID number must be referenced. Without the unique user fee ID number, the payment may not be applied. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: July 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15906 Filed 7–25–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1771]

Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions; 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 ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions.'' This guidance provides recommendations for information and testing that should be included in 510(k) submissions for metal expandable biliary stents and their associated delivery systems intended to provide luminal patency of malignant strictures in the biliary tree.

DATES: The announcement of the guidance is published in the **Federal Register** on July 26, 2019.

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–2018–D–1771 for ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions.'' 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.

• 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.gpo.gov/fdsys/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.

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 single hard copy of the guidance document entitled ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: April Marrone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G218, Silver Spring, MD 20993–0002, 240–402–6510.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations for 510(k) submissions for metal expandable biliary stents and their associated delivery systems. These devices are intended to provide luminal patency of malignant strictures in the biliary tree. The scope of this guidance is limited to metal expandable biliary stents regulated under 21 CFR 876.5010 (*Biliary catheter and accessories*) and with product code FGE (Catheter, Biliary, Diagnostic). This guidance applies only to biliary stents indicated for palliation of malignant strictures in the biliary tree. It does not apply to biliary stents indicated to treat benign strictures or stents intended to be used in the vasculature, tracheal/bronchial tubes, or other gastrointestinal anatomy.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of July 18, 2018 (83 FR 33940). FDA revised the guidance as appropriate in response to the comments. This guidance updates and supersedes the guidance ''Guidance for the Content of Premarket Notifications for Metal Expandable Biliary Stents,'' issued on February 5, 1998, to reflect current review practices.

II. Significance of Guidance

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 ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions.'' 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. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Metal Expandable Biliary Stents—Premarket Notification (510(k)) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500070 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These 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. 3501–3520). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
801	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
56	Institutional Review Boards	0910–0130

Dated: July 22, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15889 Filed 7–25–19; 8:45 am]

BILLING CODE 4164–01–P

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; Rural Communities Opioid Response Program Performance Measures, OMB No. 0906-xxxx, New.

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

ACTION: Notice.

SUMMARY: In compliance with of 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.

DATES: Comments on this ICR should be received no later than August 26, 2019.

ADDRESSES: Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

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: Rural Communities Opioid Response Program Performance Measures, OMB No. 0906-xxxx, New

Abstract: The Rural Communities Opioid Response Program (RCORP) is a multi-initiative program that aims to: (1) Support treatment for, and prevention of, substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, to include OUD, by improving access to prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP-Planning grants to strengthen the capacity of multi-sector consortia to collaborate and develop plans to deliver SUD/OUD prevention, treatment, and recovery services in high-risk rural communities;
- RCORP-Implementation grants to fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities; and
- RCORP-Medication Assisted Treatment Expansion grants to enhance access to medication-assisted treatment within eligible hospitals, health clinics, or tribal organizations in high-risk rural communities.

Additionally, all RCORP grant award recipients will be supported by five cooperative agreements: RCORP-Technical Assistance, which provides extensive technical assistance to award recipients; RCORP-Evaluation, which will evaluate the impact of the RCORP initiative on rural communities; and three RCORP-Rural Centers of Excellence in Substance Use Disorders, which will disseminate best practices related to the treatment for, and prevention of, SUD within rural communities. A 60-day notice was published in the **Federal Register** on April 12, 2019, vol. 84, No. 71; pp. 14949–14950. There were no public comments.

Need and Proposed Use of the Information: For this program, performance measures were developed to provide data on each RCORP initiative and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Provision of, and referral to, SUD treatment and support services; (b) SUD prevention, treatment, and recovery process and outcomes; (c) education of health care providers and community members; (d) number of fatal and non-fatal opioid-related overdoses; and (e) consortium strength and sustainability. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents will be the grant award recipients of RCORP initiatives.

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.