were not manufacturing or processing such drug products; and (5) facilities that, at the close of FY 2023, remain on the arrears list for failure to satisfy the FY 2021, FY 2022, or FY 2023 facility fee are likely to be placed on the FY 2024 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,102 OMUFA fee-paying units. The Agency estimates that 57 percent ($1{,}102 \times 0.57 = 628$, rounded) will incur the MDF fee and 43 percent ($1{,}102 \times 0.43 = 474$, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (628) and a value of ⅔ to each CMO ($474 \times ⅔ = 316$) for a full facility equivalent of 944 (rounded). The target fee revenue of $32,253,000 is then divided by 944 for an MDF fee of $34,166 and a CMO fee of $22,777.

V. Fee Schedule for FY 2024

The fee rates for FY 2024 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2024

Fee category	FY 2024 Fee rates
Facility Fees:	
MDF	$34,166
CMO	22,777

VI. Fee Payment Options and Procedures

The new facility fee rates are for the period from October 1, 2023, through September 30, 2024. To pay the MDF and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp.*

A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph 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 through *https://userfees.fda.gov/pay.* 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 that are 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.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in consequences of nonpayment per section 744M(e)(1) of the FD&C Act. 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 account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

If you are assessed an FY 2024 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in this notice, please contact *CDERCollections@fda.hhs.gov.*

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06723 Filed 3–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1242]

Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions; Draft 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 the draft guidance entitled ''Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions.'' This draft guidance document provides animal study design recommendations and animal study information to include to support a 510(k) submission for dental bone grafting material devices. This draft guidance may help manufacturers comply with some special controls for dental bone grafting material devices. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2024 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 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–2024–D–1242 for ''Animal Studies for Dental Bone Grafting Material Devices—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, 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 single hard copy of the draft guidance document entitled ''Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions'' to the Office of Policy, 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: Joel Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G234, Silver Spring, MD 20993–0002, 301–796–6520.

SUPPLEMENTARY INFORMATION:

I. Background

A dental bone grafting material device is a material that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region. This draft guidance document provides premarket notification (510(k)) submission recommendations for animal studies that may help manufacturers comply with the in vivo performance special control identified in FDA's guidance, ''Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices'' (*https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/dental-bone-grafting-material-devices-class-ii-special-controls-guidance-industry-and-fda-staff*) for dental bone grafting material devices. This draft guidance document also provides recommendations for manufacturers who choose to combine an animal study that evaluates in vivo safety and performance of the dental bone grafting material with a biocompatibility evaluation of implantation (or the local effects after implantation) to help reduce the total number of animals used to support the 510(k) submission. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Animal Studies for Dental Bone Grafting Material Devices—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.

II. Electronic Access

Persons interested in obtaining a copy of the draft 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* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*. Persons unable to download an electronic copy of ''Animal Studies for Dental Bone Grafting Material Devices—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 GUI00007042 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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 the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120

21 CFR part or guidance	Topic	OMB control No.
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06734 Filed 3–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, May 9, 2024, from 10 a.m. to 5 p.m. eastern time (ET) and Friday, May 10, 2024, from 10 a.m. to 3 p.m. ET.

ADDRESSES: This meeting will be held in person with webcast options. While this meeting is open to the public, advance registration is required.

Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html* by the deadline of 12 p.m. ET on Wednesday, May 8, 2024. Instructions on how to access the meeting via webcast will be provided upon registration.

If you are a non-U.S. citizen who would like to attend the May meeting in-person, please contact *ACHDNC@hrsa.gov* by April 19, 2024.

FOR FURTHER INFORMATION CONTACT: Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room, Rockville, Maryland 20857; 301–443–6672; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

During the May 9–10, 2024, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items may include the following topics:

(1) A possible presentation on drug trials for rare diseases;

(2) A possible presentation on assessing evidence from qualitative research using the GRADE–CERQUAL approach;

(3) Updates from Committee ad hoc topic groups. Potential topics include: the nomination process and revisions to the decision matrix, counting conditions, and naming conditions;

(4) An update on the evidence review of Duchenne Muscular Dystrophy (DMD), which was previously nominated for Committee consideration; and

(5) Following the DMD evidence review presentation, a potential vote on whether to recommend to the Secretary the addition of DMD to the Recommended Uniform Screening Panel at this time or to take other Committee action regarding this nominated condition. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments on any or all of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12 p.m. ET on Friday, April 26, 2024. Written comments will be shared with the Committee prior to the meeting so that they have an opportunity to consider them in advance of the meeting.

Individuals who need special assistance or another reasonable accommodation should notify Kim Morrison at the address and phone number listed above at least 10 business days prior to the meeting.

Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 15 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–06689 Filed 3–28–24; 8:45 am]

BILLING CODE 4165–15–P