FDA has also published guidance on export certification that contains useful information that applies to export lists: ''FDA Export Certification'' (August 2021) available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification.*

Foreign governments are increasingly relying on certification as a strategy for ensuring the safety of imported food products, and many countries have announced new requirements for lists of establishments and products certified to comply with certain food safety requirements. FDA is committed to facilitating compliance with new listing requirements for U.S. establishments that export FDA-regulated food products by establishing and maintaining country- and product-specific export lists.

Application for inclusion on all export lists will continue to be voluntary. However, some foreign governments may require inclusion on export lists as a precondition for market access or to satisfy other importing country registration or approval requirements. FDA uses the Export Listing Module (ELM), an electronic system (Form FDA 3972), to receive and process applications for inclusion on export lists for HFP-regulated products. The ELM allows applicants to provide information about the products intended for export, the establishment that produces those products, evidence of the establishment's compliance with applicable requirements for the products intended for export, and any additional data or information (such as third-party certifications) that foreign governments may require. We request that this information be updated every 2 years. Additional information and screenshots of the ELM are available at *https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists.* If an establishment is unable to submit an application via the ELM, it may contact HFP and request assistance.

We use the information submitted by establishments to determine eligibility for certification and inclusion on the export lists, which may be published on our website or the websites of foreign governments. The purpose of the lists is to help HFP-regulated industries meet the import requirements of foreign governments. This collection of information is intended to cover all of HFP's existing export lists, as well as any additional export lists established by the program.

FDA notes section 801 of the FD&C Act (21 U.S.C. 381) also provides that FDA may charge a fee of up to $175 if the Agency issues export certification within 20 days of receipt of a complete request for such certification.

Description of Respondents: Respondents to this collection of information include U.S. establishments subject to FDA/HFP jurisdiction that wish to be included on export lists.

In the **Federal Register** of May 1, 2025 (90 FR 18688), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received two comments, believing one to have been posted erroneously to docket FDA–2025–N–0183 because it discussed vaccines. The second comment offered general support for the information collection and suggested technical enhancements to FDA's collection mechanisms. Because FDA developed the ELM to facilitate the export of food and avoid delay, we appreciate this comment. At the same time, we are only able to make updates to our automated systems as our limited resources allow. We made no adjustment to our estimate after review of the public comments.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

IC activity recommended by guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
New request	167	5	835	1	835
New request + third-party certification	85	2	170	22	3,740
Biennial update	132	4	528	0.5 (30 minutes)	264
Biennial update + third-party certification	58	2	116	22	2,552
Occasional updates	60	2	120	0.5 (30 minutes)	60
Total			1,769		7,451

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: August 15, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16075 Filed 8–21–25; 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; 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 ''Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions.'' This guidance document provides recommendations for animal study design and animal study information to include to support a 510(k) submission for dental bone grafting material devices. This 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.

DATES: The announcement of the guidance is published in the **Federal Register** on August 22, 2025.

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–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 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. 5441, 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 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 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 the implantation endpoint (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.

A notice of availability of the draft guidance appeared in the **Federal Register** of March 29, 2024 (89 FR 22160). FDA considered comments received and revised the guidance as appropriate in response to the comments, including minor clarifications to the animal study design recommendations for the evaluation of dental bone grafting material devices and providing additional reference citations.

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 ''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 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
''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

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–16137 Filed 8–21–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0414]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Reagents for Detection of Specific Novel Influenza A Viruses

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 22, 2025.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0584. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Reagents for Detection of Specific Novel Influenza A Viruses—21 CFR Part 866

OMB Control Number 0910–0584—Extension

This information collection was established as a special control for the class II device type, Novel Influenza A Reagents. In accordance with section 513 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c), FDA evaluated an application for an in vitro diagnostic device for detection of influenza subtype H5 (Asian lineage), commonly known as avian flu. FDA concluded that this device is properly classified into class II in accordance with section 513(a)(1)(B) of the FD&C Act, because it is a device for which the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but there is sufficient information to establish special controls to provide such assurance. The statute permits FDA to establish as special controls many different things, including postmarket surveillance, development and dissemination of guidance recommendations, and ''other appropriate actions as the Secretary [of HHS] deems necessary'' (section 513(a)(1)(B) of the FD&C Act). This information collection is a measure that FDA determined to be necessary to provide reasonable assurance of safety and effectiveness of reagents for detection of specific novel influenza A viruses.

FDA issued an order classifying the H5 (Asian lineage) diagnostic device into class II on March 22, 2006 (71 FR 14377), establishing the special controls necessary to provide reasonable assurance of the safety and effectiveness of that device and similar future devices. The new classification was codified in 21 CFR 866.3332, a regulation that describes the new classification for reagents for detection of specific novel influenza A viruses and sets forth the special controls that help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation refers to the document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' (March 2006) which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. The guidance document is available on our website at: *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-*