requires that each institution also provide a copy of the notice to the servicer of the loan (if different from the originating lender). Section 100239 of the Biggert-Waters Flood Insurance Reform Act of 2012 requires each federal banking agency (including the FDIC), and the Farm Credit Administration, to adopt implementing regulations to direct regulated lending institutions to accept ''private flood insurance,'' as defined by the Biggert-Waters Act. A lending institution would be required to implement policies and procedures to comply with the Biggert-Waters Act provision and verify in writing that a private insurance policy satisfies the criteria included in the definition or document findings that separate required criteria have been met when accepting a private flood insurance policy in satisfaction of the mandatory flood insurance purchase requirement of the Flood Disaster Protection Act. The institution must also maintain records to permit examination staff to ascertain how the institution has met the requirements of the regulation.

The FDIC has reviewed its previous submission related to the PRA and has updated its methodology to align with the Office of the Comptroller of the Currency's corresponding information collection (1557–0326). The decrease in the estimated annual burden of 409,935 hours is the result of this change in methodology.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, on April 5, 2022.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2022–07639 Filed 4–8–22; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0552]

Safety and Performance Based Pathway Device-Specific Guidances; 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 two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' The device-specific guidances identified in this notice were developed in accordance with the finalized guidance entitled ''Safety and Performance Based Pathway.''

DATES: The announcement of the guidances is published in the **Federal Register** on April 11, 2022.

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–2022–D–0552 for ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' 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 documents are available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidances. Submit written requests for a single hard copy of the guidance document entitled ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' or the guidance document entitled ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway; Guidance for Industry and Food and Drug Administration Staff'' 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: Jason Ryans, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1613, Silver Spring, MD 20993–0002, 301–796–4908.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA is announcing the availability of two final device-specific guidance documents for the Safety and Performance Based Pathway—specifically, ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' These device-specific guidance documents provide performance criteria for premarket notification (510(k)) submissions to support the optional Safety and Performance Based Pathway, as described in the guidance entitled ''Safety and Performance Based Pathway.'' [1] As described in that guidance, substantial equivalence is rooted in comparisons between new devices and predicate devices. However, the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not preclude FDA from using performance criteria to facilitate this comparison. If a legally marketed device performs at certain levels relevant to its safety and effectiveness, and a new device meets those levels of performance for the same characteristics, FDA could find the new device as safe and effective as the legally marketed device. Instead of reviewing data from direct comparison testing between the two devices, FDA could support a finding of substantial equivalence with data demonstrating the new device meets the level of performance of an appropriate predicate device(s). Under this optional Safety and Performance Based Pathway, a submitter of a surgical suture or orthopedic fracture fixation plate device could satisfy the requirement to compare its device with a legally marketed device by, among other things, independently demonstrating that the device's performance meets performance criteria as established in the relevant above-listed guidance rather than using direct predicate comparison testing for some of the performance characteristics.

These guidances are being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). FDA has determined that these guidance documents present less burdensome policies that are consistent with public health. Although these guidances are being implemented immediately, FDA will consider all comments received and revise the guidance documents as appropriate.

These guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These guidances represent the current thinking of FDA on ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' and ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway.'' They do not establish any rights for any person and are 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 guidances 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.* These guidance documents are also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 20002 for ''Surgical Sutures—Performance Criteria for Safety and Performance Based Pathway'' or document number 19044 for ''Orthopedic Fracture Fixation Plates—Performance Criteria for Safety and Performance Based Pathway'' to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While these guidances contain no new collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulation and guidance have been approved by OMB as listed in the following table:

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

[1] Available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway.*

21 CFR part; guidance	Topic	OMB control No.
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program".	Q-submissions; pre-submissions	0910–0756

Dated: April 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–07684 Filed 4–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5225]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Foreign Supplier Verification Programs for Food Importers

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: Fax written comments on the collection of information by May 11, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0752. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–45, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Foreign Supplier Verification Programs (FSVP) for Food Importers—21 CFR Part 1, Subpart L

OMB Control Number 0910–0752—Extension

This information collection supports FDA regulations in 21 CFR part 1, subpart L (21 CFR 1.500 through 1.514 (§§ 1.500 through (§§ 1.514)), which help to implement section 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384a). Section 805 authorizes the Agency's FSVP and establishes requirements applicable to imported food. Respondents to the information collection are importers, as defined in section 805(a)(1) of the FD&C Act. The regulations are intended to provide verification that imported food is produced in compliance with statutory requirements that include the implementation of appropriate risk-based preventive controls. The regulations also establish that importers of foods must develop, maintain, and follow an FSVP that provides adequate assurances a foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under section 418 of the FD&C Act (21 U.S.C. 350g) (regarding hazard analysis and risk-based preventive controls for certain foods) or 419 (21 U.S.C. 350h) (regarding standards for produce safety), if either is applicable, and the implementing regulations, and is producing the food in compliance with sections 402 (21 U.S.C. 342) (regarding adulteration) and 403(w) (21 U.S.C. 343(w)) (if applicable) (regarding misbranding with respect to labeling for the presence of major food allergens) of the FD&C Act. The regulations also provide for certain exemptions. To assist respondents with understanding the requirements we have developed Agency guidance, available at: *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-foreign-supplier-verification-programs-fsvp-importers-food-humans-and-animals.*

Specifically, regulations in § 1.501 set forth the applicability of requirements for FSVP, while regulations in §§ 1.502 through 1.508, prescribe specific activities for developing, maintaining, and following an FSVP; as well as for evaluating compliance and for identifying and correcting hazards. Finally, regulations in § 1.509 identify required data elements applicable to food products offered for importation into the United States, while regulations in § 1.510 govern required records, providing that records be made available to FDA upon request and that records be maintained electronically. On May 10, 2021, FDA launched the FSVP Importer Portal for FSVP Records Submission as a means for importers to upload FSVP records electronically and submit them to the Agency, after receiving a request for records from FDA. The portal may be found at *https://www.access.fda.gov/,* and a user guide is available at *https://www.fda.gov/media/148312/download.*

In the **Federal Register** of January 28, 2022 (87 FR 4607), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Exemption for food for research; 1.501(c)	36,360	40	1,454,400	0.083 (5 minutes)	120,715
Identifier for filing with U.S. Customs and Border Protection; 1.509.	56,800	157	8,917,600	0.02 (1.2 minutes)	178,352
Total			10,372,000		299,067

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