

existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Agreement for Shipment of Devices for Sterilization—21 CFR 801.150**

**OMB Control Number 0910-0131—Extension**

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are

labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on data obtained from industry over the past several years. It is estimated that each of the firms subject to this requirement prepares an average of 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

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

**TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>**

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Record retention, 801.150(a)(2) .....	100	20	2,000	.5	1,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

**TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN<sup>1</sup>**

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e) .....	100	20	2,000	4	8,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 900 total hours and a corresponding increase of 400 records/disclosures. We attribute this increase to an increase in the number of agreements that we have seen in inspection data received over the last few years.

Dated: April 23, 2019.

**Lowell J. Schiller,**  
Principal Associate Commissioner for Policy.  
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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-D-1329]

**Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket 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 "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions." FDA has developed this document to describe relevant information that should be included in test report summaries, test protocols, and complete test reports for non-clinical bench performance testing provided in a premarket submission

(i.e., premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification (510(k)) submissions, investigational device exemption (IDE) applications, and De Novo requests).

**DATES:** The announcement of the guidance is published in the **Federal Register** on April 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-1329 for "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket 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 "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket 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:**

Jismi Johnson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993-0002, 301-796-6424.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of the guidance for industry and FDA staff entitled "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions." FDA has developed this document to describe relevant information that should be included in test report summaries, test protocols, and complete test reports for non-clinical bench performance testing provided in a premarket submission (i.e., PMA, HDE applications, 510(k) submissions, IDE applications, and De Novo requests).

Non-clinical bench performance testing is defined as performance testing, performed by either a device manufacturer or a third-party testing facility (e.g., test laboratory), which encompasses all bench testing and will be dependent upon the specifics of the actual device or device type. Non-clinical bench performance testing includes, but is not limited to, mechanical and biological engineering performance (such as fatigue, wear, tensile strength, compression, burst pressure); bench tests using ex vivo, in vitro, and in situ animal or human tissue; and animal carcass or human cadaveric testing.

Non-clinical bench performance testing excludes biocompatibility evaluation, reprocessing or sterilization validation, human factors, software verification and validation, and computational modeling because relevant information on these assessments are included in associated guidance documents. Test reports for clinical studies, animal studies, and studies evaluating the performance characteristics of in vitro diagnostic devices are also excluded from the scope of this document.

This guidance is intended to help ensure that clear and consistent information is provided in premarket submissions containing non-clinical bench performance testing. The information in this guidance is intended

to be used in conjunction with other FDA guidance documents, including device-specific guidances, as well as in conjunction with specific test reporting recommendations in FDA-recognized standards.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of May 31, 2018 (83 FR 25014). FDA revised the guidance as appropriate in response to the comments.

**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 recommended content and format of non-clinical bench performance testing information in premarket 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “Recommended Content and Format

of Non-Clinical Bench Performance Testing Information in Premarket Submissions” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 18011 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 and guidance have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E .....	Premarket notification .....	0910–0120
814, subparts A through E .....	Premarket approval .....	0910–0231
814, subpart H .....	Humanitarian Device Exemption .....	0910–0332
812 .....	Investigational Device Exemption .....	0910–0078
“De Novo Classification Process (Evaluation of Automatic Class III Designation)” ...	De Novo classification process .....	0910–0844

Dated: April 23, 2019.

**Lowell J. Schiller,**  
Principal Associate Commissioner for Policy.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Vaccine Injury Compensation Program: List of Petitions Received**

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

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

**FOR FURTHER INFORMATION CONTACT:** For information about requirements for

filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA’s role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443–6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

**SUPPLEMENTARY INFORMATION:** The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from

vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.” Set forth below is a list of petitions received by HRSA on March 1, 2019, through March 31, 2019. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to