

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Residents, first responders, business owners, employees, customers.	Eligibility Screener .....	900	1	2/60	30
	Epi CASE Survey .....	1,000	1	15/60	250
	General Survey .....	800	1	25/60	333
Residents .....	Household Survey .....	120	1	10/60	20
Hospital staff .....	Hospital Survey .....	40	1	25/60	17
Staff from state, local, or tribal health agencies.	Medical Chart Abstraction Form .....	25	10	30/60	125
Total .....	.....	.....	.....	.....	775

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0672]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reprocessed, single-use device labeling.

**DATES:** Submit either electronic or written comments on the collection of information by April 26, 2021.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 26, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 26, 2021. Comments

received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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-2011-N-0672 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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://](https://www.regulations.gov)

[www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf](http://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.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an 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.

**Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices**

*OMB Control Number 0910-0577—Extension*

Section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352), among other things, establishes requirements that the label or labeling of a medical device must meet so that it is not misbranded and subject to regulatory action. Section 301 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 502 of the FD&C Act to add paragraph (u) to require devices (both new and reprocessed) to bear prominently and conspicuously the name of the manufacturer, a generally recognized abbreviation of such name, or a unique and generally recognized symbol identifying the manufacturer.

Section 2(c) of the Medical Device User Fee Stabilization Act of 2005 (MDUFSA) (Pub. L. 109-43) amends section 502(u) of the FD&C Act by limiting the provision to reprocessed single-use devices (SUDs) and the manufacturers who reprocess them. Under the amended provision, if the original SUD or an attachment to it prominently and conspicuously bears the name of the manufacturer, then the

reprocessor of the SUD is required to identify itself by name, abbreviation, or symbol in a prominent and conspicuous manner on the device or attachment to the device. If the original SUD does not prominently and conspicuously bear the name of the manufacturer, the manufacturer who reprocesses the SUD for reuse may identify itself using a detachable label that is intended to be affixed to the patient record.

As directed by MDUFSA, FDA issued the guidance entitled "Compliance with Section 301 of the Medical Device User Fee and Modernization Act of 2002, as amended—Prominent and Conspicuous Mark of Manufacturers on Single-Use Devices" (<https://www.fda.gov/media/71187/download>) to identify circumstances in which the name or symbol of the original SUD manufacturer is not prominent and conspicuous, as used in section 502(u) of the FD&C Act. However, the guidance does not contain additional information collections.

The requirements of section 502(u) of the FD&C Act impose a minimal burden on industry. This section of the FD&C Act only requires the manufacturer, packer, or distributor of a device to include their name and address on the labeling of a device. This information is readily available to the establishment and easily supplied. From FDA's Unified Registration and Listing System database, FDA estimates that there are 175 establishments that distribute approximately 946 reprocessed SUDs. The majority of establishments (161) distribute an average of 2 SUDs per establishment. The remaining 14 establishments distribute an average of 45 SUDs per establishment. Each response is anticipated to take 0.1 hours (6 minutes).

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

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

Type of respondent	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Establishments listing less than 10 SUDs .....	161	2	322	0.1	32
Establishments listing 10 or more SUDs .....	14	45	630	0.1	63
Total .....					95

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

<sup>2</sup> Totals may not sum due to rounding.

Our estimated burden for the information collection reflects an increase of 52 hours. We attribute this adjustment to an increase in the number of establishments and reprocessed SUDs.

Dated: February 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021-03748 Filed 2-23-21; 8:45 am]

BILLING CODE 4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-7012]

#### **Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 March 26, 2021.

**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 0910-0850. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Use of Public Human Genetic Variant Databases To Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics**

*OMB Control Number 0910-0850—Extension*

Section 2011 of the 21st Century Cures Act of 2016 (Pub. L. 114-255) encourages the FDA to develop new approaches for addressing regulatory science issues as part of the Precision Medicine Initiative (PMI).

In the **Federal Register** of April 13, 2018 (83 FR 16110), FDA announced the availability of a guidance for industry entitled “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics; Guidance for Stakeholders and Food and Drug Administration Staff.”<sup>1</sup> The guidance describes one part of FDA’s PMI effort to create a flexible and adaptive regulatory approach to the oversight of next generation sequencing (NGS)-based tests. The goal of this effort is to help ensure patients receive accurate and meaningful test results, while promoting innovation in test development. The guidance describes how publicly accessible databases of human genetic variants can serve as sources of valid scientific evidence to support the clinical validity of genotype-phenotype relationships in FDA’s regulatory review of both NGS-based tests and genetic and genomic tests based on other technologies. Publicly accessible genetic databases may be useful to support the clinical validity of NGS tests as well as single gene or panel tests that use other technology.

The guidance describes FDA’s considerations in determining whether a genetic variant database is a source of valid scientific evidence that could support the clinical validity of an NGS-based test. The guidance further outlines the process by which administrators<sup>2</sup> of genetic variant databases could voluntarily apply to FDA for recognition, and how FDA

<sup>1</sup> Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-public-human-genetic-variant-databases-support-clinical-validity-genetic-and-genomic-based-vitro>.

<sup>2</sup> FDA acknowledges that many databases may not use the term “administrator” or may have a committee of individuals that oversee the database. Therefore, for the purpose of this guidance, a genetic variant database administrator is the entity or entities that oversee database operations.

would review such applications and periodically reevaluate recognized databases. The guidance also recommends that, at the time of recognition, the database administrator make information regarding policies, procedures, and conflicts of interest publicly available and accessible on the genetic variant database’s website.

Respondents are administrators of genetic databases. Our estimate of five respondents per year is based on the current number of databases that may meet FDA recommendations for recognition and seek such recognition.

Based on our experience and the nature of the information, we estimate that it will take an average of 80 hours to complete and submit an application for recognition. We estimate that maintenance of recognition activities will take approximately one-fourth of that time (20 hours) annually. We estimate that it will take approximately 1 hour to post the information on the website.

In the **Federal Register** of September 23, 2020 (85 FR 59801), we published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments. One comment was not relevant to the topic or information collection. A summary of the other comment and our response are as follows:

(Comment) One comment expressed concerns and suggestions regarding the collection, storage, and security of personally identifiable information (PII) and protected health information (PHI).

(Response) The guidance document “Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics” describes, among other things, FDA’s considerations in determining whether a publicly accessible genetic variant database is a source of valid scientific evidence that could support the clinical validity of genetic and genomic-based tests in a premarket submission and outlines the process by which administrators of publicly accessible genetic variant databases could voluntarily apply to FDA for recognition, and how FDA would assess such applications and periodically reevaluate recognized databases. FDA recommends that genetic database administrators should identify the applicable laws and regulations to assure that any requirements are addressed and transparently documented. Genetic variant database administrators should also put in place adequate security measures to ensure the protection and privacy of PII and PHI and provide