and Budget (OMB) for each collection of information they conduct or sponsor.

The term “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. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

**Information Collection**

1. **Type of Information Collection Request:** Revision of a currently approved collection; **Title of Information Collection:** Statement of Deficiency and Plan of Correction **Use:** The form CMS–2567 is the means by which State and CMS surveyors document findings of compliance or noncompliance (deficiencies) resulting from inspection of Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) laboratories. The form CMS–2567 is the legal, documentary basis for CMS’ certification of a facility’s compliance or noncompliance with the Medicare/Medicaid Conditions of Participation or Coverage, and the requirements for Nursing Home participation and CLIA certification.

   In December, 2020, Congress passed the Consolidated Appropriations Act, 2021 (CAA, 2021), Section 407 of CAA, 2021, amended Part A of Title XVIII of the Social Security Act (the Act) at section 1822 establishing hospice program survey and enforcement requirements. This amendment, in part, now requires the Accrediting Organizations (AOs) that accredit hospice programs to include the form CMS–2567 to document the findings of their hospice program surveys beginning on October 1, 2021. As of June 2021, there are three AOs with CMS-approved hospice accreditation programs. The AOs survey approximately half of the over 5,000 Medicare-certified hospice programs, while the SAs survey the remaining half.

   To enable AOs to use the form CMS–2567, we must revise it by adding fields for the AO name. Also, the instructions must be updated to include AOs as another group which utilizes the form CMS–2567. We have also included the burden calculations from CMS–1747–P (Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update), related to the one-time update needed to each of AO’s proprietary electronic systems in order to use the form CMS–2567 as directed by the CAA, 2021. **Form Numbers:** CMS–2567 (OMB control number: 0938–0391); **Frequency:** Yearly and Occasionally; **Affected Public:** Private Sector (Business or for-profits and Not-for-profit institutions); **Number of Respondents:** 65,948; **Total Annual Responses:** 65,948; **Total Annual Hours:** 1,210,376. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

   **Dated:** July 8, 2021.

   **William N. Parham, III,**
   **Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2019–N–0895]

**Issuance of Priority Review Voucher; Material Threat Medical Countermeasure Product**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a material threat medical countermeasure (MCM) product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the 21st Century Cures Act (Cures Act), authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher.

FDA has determined that STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), manufactured by Stratatech, a Mallinckrodt Company, meets the criteria for a material threat MCM priority review voucher.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the issuance of a material threat MCM priority review voucher to the sponsor of an approved material threat MCM product application. Under section 565A of the FD&C Act (21 U.S.C. 360bbb–4a), which was added by the Cures Act (Pub. L. 114–255), FDA will award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria upon approval of those applications. FDA has determined that STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), manufactured by Stratatech, a Mallinckrodt Company, meets the criteria for a material threat MCM priority review voucher.


**Dated:** July 6, 2021.

**Lauren K. Roth,**
**Acting Principal Associate Commissioner for Policy.**

**BILLING CODE 4164–01–P**

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1048]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Labeling Regulations**

**AGENCY:** Food and Drug Administration, Health and Human Services (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 information collection associated with medical
device labeling regulations.

DATES: Submit either electronic or
written comments on the collection of
information by September 13, 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 September 13,
federal filing system will accept
comments until 11:59 p.m. Eastern Time
at the end of September 13, 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
detailed in “Instructions.”

Instructions: All submissions received
must include the Docket No. FDA–
2014–N–1048 for “Agency Information
Collection Activities; Proposed
Collection; Comment Request; Medical
Device Labeling Regulations.” Received
comments, those filed in a timely
manner (see ADDRESSES), will be placed in
the docket and, except for those
submissions 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 the comments and you
must identify this information as
“confidential.” Any information marked
“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-

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,

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, PRAS@

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.

Medical Device Labeling Regulations
OMB Control No. 0910–0485—Revision
This information collection supports
implementation of medical device
labeling requirements governed by
section 502 of the Federal Food, Drug,
and Cosmetic Act (FD&C Act) [21 U.S.C.
352], codified in Agency regulations,
and discussed in associated Agency
guidance. Medical device labeling
requirements, among other things,
provide for the label or labeling content
of a medical device so that it is not
misrepresented or misused. Certain
provisions under section 502 of the FD&C Act require that
manufacturers, importers, and distributors of medical devices disclose information about themselves or the devices on the labels or labeling for the devices. Section 502 provides, in part, that a device shall be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use. Medical device labeling regulations in parts 800, 801, 809, and associated regulations in part 1040 (21 CFR parts 800, 801, 809, and 1040), prescribe the disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves and/or the devices, on the label or labeling for the devices, to health professionals and consumers.

In conjunction with provisions in part 800, part 801, subpart A sets forth general labeling provisions applicable to all medical devices, including content and format requirements pertaining to intended uses, adequate directions for use, misleading statements, and the prominence of required labeling. Information collection provisions found in part 801, subpart B pertaining to labeling requirements for Unique Device Identification are currently approved under OMB control number 0910–0720 and not covered in this information collection request. Information collection associated with labeling requirements for Over-the-Counter (OTC) Devices are found in part 801, subpart C, and cover principal display panel; statement of identity; declaration of net quantity of contents; and certain warning statement elements. Information collection associated with exemptions from adequate directions for use and other exemptions are found in part 801, subparts D and E, respectively. Information collection associated with special labeling requirements applicable to specific devices are found in part 801, subpart H. We also include information collection associated with labeling for in vitro diagnostic products for human use, as set forth in part 809, subpart B. Finally, in addition to the labeling requirements in part 801 and the certification and identification requirements of 21 CFR 1010.2 and 1010.3, sunlamp products and ultraviolet lamps are subject to specific labeling requirements as set forth in part 1040.

We have revised the information collection to include reference to Agency guidance. The guidance documents were developed and issued consistent with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

Section 502(b) of the FD&C Act requires that, for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor; and an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may, however, grant an exemption if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case as it relates to protection of the public health. 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 section 502 to require devices (both new and reprocessed) to bear prominently and conspicuously the name, abbreviation, or symbol 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 and Modernization Act of 2005 (MDUFSA) amended 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 the 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. MDUFSA required that FDA issue guidance identifying the circumstances in which the name, abbreviation, or symbol of the manufacturer of an original device is not “prominent and conspicuous” under section 502(u) of the FD&C Act. Accordingly, we issued the guidance document 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” (May 2006), available at https://www.fda.gov/media/71187/download. The guidance document is intended 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. We believe the information disclosures discussed in the guidance impose no burden beyond that which we attribute already to complying with disclosure provisions found in the applicable regulations; however, we include the guidance document for respondents’ instructional use and reference.

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbols glossary</td>
<td></td>
<td></td>
<td>3,000</td>
<td>1</td>
<td>3,000</td>
</tr>
</tbody>
</table>

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

Our figures are based on data from the FDA Unified Registration and Listing System and the OASIS shipment information. FDA allows the use of stand-alone graphical representations of information, or symbols, in the labeling for the medical devices, if the symbol has been established in a Standards Development Organization developed standard, provided that such symbol is explained in a symbols glossary that is included in the labeling for the medical device and otherwise complies with section 502 (misbranding) of the FD&C Act.
As set forth in §801.150(a)(2) (21 CFR 801.150(a)(2)), device manufacturers are required to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the final shipment or delivery of the device. Section 801.150(a)(2) requires that copies of this agreement be made available upon request by any officer or employee of the Department of Health and Human Services (HHS). In §801.410(e) (21 CFR 801.410(e)) copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, are required to be maintained for 3 years by the retailer and made available upon request by any officer or employee acting on behalf of the Secretary of HHS.

Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years. Specific recordkeeping requirements applicable to hearing aid dispensers, manufacturers of menstrual tampons, and manufacturers of latex condoms are set forth in 21 CFR 801.421(d), 801.430(f), and 801.435(g), respectively.

### Table 2—Estimated Annual Recordkeeping Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processing, labeling, or repacking agreement; 801.150.</td>
<td>7,500</td>
<td>887</td>
<td>6,652,500</td>
<td>0.5 (30 minutes) ..................</td>
<td>3,326,250</td>
</tr>
<tr>
<td>Impact resistant lenses; invoices, shipping documents, and records of sale or distribution; 801.410(e) and (f).</td>
<td>1,591</td>
<td>47,050</td>
<td>74,856,550</td>
<td>0.0008 (0.048 minutes) ..........</td>
<td>59,885</td>
</tr>
<tr>
<td>Hearing aid records; 801.421</td>
<td>10,000</td>
<td>160</td>
<td>1,600,000</td>
<td>0.25 (15 minutes) ................</td>
<td>400,000</td>
</tr>
<tr>
<td>Menstrual tampons, sampling plan for measuring absorbency; 801.430(f).</td>
<td>33</td>
<td>11</td>
<td>363</td>
<td>80 (no burden per recordkeeping)</td>
<td>29,040</td>
</tr>
<tr>
<td>Latex condoms; justification for the application of testing data to the variation of the tested product; 801.435(g).</td>
<td>51</td>
<td>3.65</td>
<td>186</td>
<td>1 (no burden per recordkeeping)</td>
<td>186</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>83,109,599</td>
<td></td>
<td>3,815,361</td>
</tr>
</tbody>
</table>

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

2 Numbers have been rounded.

### Table 3—Estimated Annual Third-Party Disclosure Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact lens cleaning solution labeling; 800.10(a)(3) and 800.12(c).</td>
<td>47</td>
<td>8</td>
<td>376</td>
<td>1 (no burden per disclosure)</td>
<td>376</td>
</tr>
<tr>
<td>Liquid ophthalmic preparation labeling; 800.10(b)(2).</td>
<td>25</td>
<td>8</td>
<td>200</td>
<td>1 (no burden per disclosure)</td>
<td>200</td>
</tr>
<tr>
<td>Manufacturer, packer, or distributor information; 801.1.</td>
<td>19,407</td>
<td>7</td>
<td>135,849</td>
<td>1 (no burden per disclosure)</td>
<td>135,849</td>
</tr>
<tr>
<td>Adequate directions for use; 801.5.</td>
<td>8,526</td>
<td>6</td>
<td>51,156</td>
<td>22.35 (30 minutes)</td>
<td>1,143,337</td>
</tr>
<tr>
<td>Statement of identity; 801.61.</td>
<td>8,526</td>
<td>6</td>
<td>51,156</td>
<td>1 (no burden per disclosure)</td>
<td>51,156</td>
</tr>
<tr>
<td>Declaration of net quantity of contents; 801.62.</td>
<td>8,526</td>
<td>6</td>
<td>51,156</td>
<td>1 (no burden per disclosure)</td>
<td>51,156</td>
</tr>
<tr>
<td>Prescription device labeling; 801.109.</td>
<td>9,681</td>
<td>6</td>
<td>58,086</td>
<td>17.77 (20 minutes)</td>
<td>1,032,188</td>
</tr>
<tr>
<td>Retail exemption for prescription devices; 801.110.</td>
<td>30,000</td>
<td>667</td>
<td>20,010,000</td>
<td>0.25 (30 minutes)</td>
<td>5,002,500</td>
</tr>
<tr>
<td>Processing, labeling, or repacking; non-sterile devices; 801.150(e).</td>
<td>453</td>
<td>34</td>
<td>15,402</td>
<td>4 (no burden per disclosure)</td>
<td>61,608</td>
</tr>
</tbody>
</table>

### Table 4—Estimated Annual Recordkeeping Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling of articles intended for lay use in the repairing and/or refitting of dentures; 801.405(b)(1).</td>
<td>35</td>
<td>1</td>
<td>35</td>
<td>4 (no burden per disclosure)</td>
<td>140</td>
</tr>
<tr>
<td>Dentures; information regarding temporary and emergency use; 801.405(c).</td>
<td>35</td>
<td>1</td>
<td>35</td>
<td>4 (no burden per disclosure)</td>
<td>140</td>
</tr>
<tr>
<td>Hearing aids professional and patient labeling; 801.420.</td>
<td>136</td>
<td>12</td>
<td>1,632</td>
<td>80 (no burden per disclosure)</td>
<td>130,560</td>
</tr>
<tr>
<td>Hearing aids, availability of User Instructional Brochure; 801.421.</td>
<td>10,000</td>
<td>5</td>
<td>50,000</td>
<td>0.17 (20 minutes)</td>
<td>8,500</td>
</tr>
<tr>
<td>User labeling for menstrual tampons; 801.430.</td>
<td>16</td>
<td>8</td>
<td>128</td>
<td>2 (no burden per disclosure)</td>
<td>256</td>
</tr>
<tr>
<td>User labeling for latex condoms; 801.437.</td>
<td>52</td>
<td>6</td>
<td>312</td>
<td>100 (no burden per disclosure)</td>
<td>31,200</td>
</tr>
</tbody>
</table>

### Table 5—Estimated Annual Third-Party Disclosure Burden

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format and content of labeling for IVDs; 809.10.</td>
<td>1,700</td>
<td>6</td>
<td>10,200</td>
<td>80 (no burden per disclosure)</td>
<td>816,000</td>
</tr>
<tr>
<td>Advertising and promotional materials for ASRs; 809.30(d).</td>
<td>300</td>
<td>25</td>
<td>7,500</td>
<td>1 (no burden per disclosure)</td>
<td>7,500</td>
</tr>
<tr>
<td>Labeling of sunlamp products—1040.20(d).</td>
<td>30</td>
<td>1</td>
<td>30</td>
<td>10 (no burden per disclosure)</td>
<td>300</td>
</tr>
</tbody>
</table>
Because many labeling provisions correspond to specific recordkeeping requirements, we have accounted for burden attendant to the provisions enumerated in table 3 as third-party disclosures. These figures reflect what we believe to be the average burden incurred by respondents to applicable information collection activities.

Overall, the information collection reflects changes and adjustments. For efficiency of operations, we have consolidated related information collection currently approved under OMB control numbers 0910–0577 and 0910–0740 pertaining to recommendations found in Agency guidance and discussed in this notice. This results in an increase to the information collection by 30,482 burden hours annually. At the same time, we have reduced our estimate of the total responses by 53,143,810 annually. Upon review, we believe we previously double-counted burden ascribed to disclosures provisions having accounted for the same burden as that associated with recordkeeping activities. We invite comment on our estimates and these assumptions.

Dated: July 2, 2021.

Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.
[FR Doc. 2021–14768 Filed 7–12–21; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Advanced Nursing Education Program Specific Form OMB No. 0915–0375—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 13, 2021.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Advanced Nursing Education (ANE) Program Specific Form OMB No. 0915–0375—Revision.

Abstract: HRSA provides advanced nursing education grants to educational institutions to increase the supply, distribution, quality of, and access to advanced education nurses through the ANE Programs. The ANE Programs are authorized by Section 811 of the Public Health Service Act (42 U.S.C. 296j), as amended. This clearance request is for continued approval of the information collection OMB No. 0915–0375 with revisions.

This revision request includes a title change from the Advanced Nursing Education Workforce (ANEW) Program-Specific Data Collection Forms to ANE Program Specific Form. This revision also merges forms used by the ANEW Program and adds several other new forms from the ANE Programs, including the Advanced Nursing Education Nurse Practitioner Residency (ANE–NPR) Program, Advanced Nursing Education Nurse Practitioner Residency Integration Program (ANE–NPRIP), Nurse Anesthetist Traineeship (NAT) Program, and Advanced Nursing Education Sexual Assault Nurse Examiners (ANE–SANE) Program. The revision of the ANE Program Specific Form incorporates elements from these four programs (ANE–NPR, ANE–NPRIP, NAT, and ANE–SANE) into the ANE Program Specific Form.

Need and Proposed Use of the Information: Section 811 of the Public Health Service Act provides the Secretary of HHS with the authority to award grants to and enter into contracts with eligible entities to meet the costs of—(1) projects that support the enhancement of advanced nursing education and practice; and (2) traineeships for individuals in advanced nursing education programs. Under this section, HRSA makes awards to entities who train and support nurses characterized as “advanced education nurses.” In awarding such grants, funding preference is given to applicants with projects that will

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TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN 1 2—Continued

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
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<tbody>
<tr>
<td>Establishments listing &lt;10 SUDs</td>
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<td>952</td>
<td></td>
<td>95</td>
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</tbody>
</table>

1 There are no capital costs or operating and maintenance costs associated with this collection of information.
2 Numbers have been rounded.