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.

[FR Doc. 2021–14866 Filed 7–12–21; 8:45 am]

BILLING CODE 4120–01–P

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 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. STRATAGRAFT is indicated for the treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated (deep partial-thickness burns).

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation.* For further information about STRATAGRAFT (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen—dsat), go to the Center for Biologics Evaluation and Research Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: July 6, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14779 Filed 7–12–21; 8:45 am]

BILLING CODE 4164–01–P

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,