- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-july-28-2021-virtual-meeting-tickets-151112584809* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: June 30, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–14830 Filed 7–12–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–2567]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is requesting that this information collection request (ICR), for revisions to the form CMS–2567 be processed under the emergency Paperwork Reduction Act of 1995 (PRA) clearance process.

DATES: Comments must be received by August 12, 2021.

ADDRESSES: When commenting, please reference the document identifier (CMS–2567) or OMB control number (0938–0391). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–R–39/OMB Control Number 0938–0365, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

FOR FURTHER INFORMATION CONTACT: William Parham, Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: 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. Public harm is reasonably likely to ensue if the normal, non-emergency clearance procedures are followed. CMS would miss the statutorily mandated deadline of October 1, 2021 for Accrediting Organizations (AOs), with a hospice program, to begin using the form CMS–2567. AOs will not have the revised form to include in their current survey documentation systems and processes and will not meet the deadline of October 1, 2021 for beginning use. If CMS misses the deadline, it will jeopardize another CAA, 2021 mandated provision deadline for public posting of these AO hospice program survey reports on our website. The purpose of this requirement is for public transparency of survey and certification information. This statutory provision requires that the hospice program survey reports be posted by no later than October 1, 2022. Additionally, the public may not have all the information necessary to make an informed decision regarding where they seek high quality, safe care hospice program organizations for themselves or loved ones. Beneficiaries and the public at large utilize survey findings when evaluating whether to receive care from certain facilities.

Under the PRA, federal agencies are required to publish notice in the **Federal Register** concerning each proposed ICR. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this ICR including the necessity and utility of the proposed ICR for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Contents

This notice sets out a summary of the use and burden associated with the following ICR. More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–2567 Statement of Deficiency and Plan of Correction

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management

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,