

heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.

On the basis of this determination, on July 9, 2018 the Secretary declared that circumstances exist justifying the authorization of emergency use of Freeze Dried Plasma (FDP) to treat uncontrolled hemorrhage due to agents of military combat (*e.g.*, firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its use is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

**DATES:** The declaration is effective July 9, 2018.

**FOR FURTHER INFORMATION CONTACT:** Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll free number).

#### **SUPPLEMENTARY INFORMATION:**

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

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear (“CBRN”) agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act<sup>1</sup> sufficient to

affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The determination of a military emergency or significant potential for a military emergency by the Deputy Secretary of Defense, and the declaration that circumstances exist justifying emergency use of French FDP by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for FDP in emergency situations when plasma is not available for use or its use is not practical for emergency use under section 564 of the FD&C Act.

##### **II. Determination of a Military Emergency or Significant Potential for a Military Emergency by the Deputy Secretary of Defense**

On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with section 564(b)(1)(B) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(1)(B), as delegated by the Secretary of Defense, that there is a military emergency or significant potential for a military emergency, involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces. The Deputy Secretary further stated that, more

specifically, U.S. Forces are now deployed in multiple locations where they serve at heightened risk of an enemy attack with agents of military combat, including firearms, projectiles, and explosive devices, that may cause major and imminently life-threatening combat casualties involving uncontrolled hemorrhage.

##### **III. Declaration of the Secretary of Health and Human Services**

On July 9, 2018, on the basis of the Deputy Secretary of Defense’s determination that there is a military emergency or significant potential for a military emergency involving a heightened risk to U.S. military forces of an attack with an agent or agents that may cause, or are otherwise associated with an imminently life-threatening and specific risk to those forces, I declared that circumstances exist justifying the authorization of emergency use of FDP to treat uncontrolled hemorrhage due to agents of military combat (*e.g.*, firearms, projectiles, and explosive devices) in emergency situations when plasma is not available for use or its use is not practical, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

**Alex M. Azar II,**  
*Secretary.*

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#### **DEPARTMENT OF HOMELAND SECURITY**

##### **U.S. Customs and Border Protection**

[Docket No. USCBP-2018-0026]

##### **Commercial Customs Operations Advisory Committee (COAC)**

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

**ACTION:** Committee management; notice of Federal Advisory Committee meeting.

**SUMMARY:** The Commercial Customs Operations Advisory Committee (COAC) will hold its public meeting on Wednesday, August 1, 2018 via webinar. The meeting will be open to the public.

**DATES:** The COAC will meet on Wednesday, August 1, 2018 from 1:00 p.m. to 4:00 p.m. EST. Please note that

<sup>1</sup> 42 U.S.C. 247d-6b, which states: “[t]he Homeland Security Secretary, in consultation with the Secretary and the heads of other agencies as appropriate, shall on an ongoing basis—(i) assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and (ii) determine which of such agents present a material

threat against the United States population sufficient to affect national security.”

the meeting may close early if the committee has completed its business.

**ADDRESSES:** The meeting will be held via webinar. The webinar link and conference phone number will be provided to all registrants by 5:00 p.m. on July 31, 2018. For information on services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs & Border Protection, at (202) 344-1440 as soon as possible.

**Pre-Registration:** Members of the public who plan to attend the meeting, please register online at: <https://teregistration.cbp.gov/index.asp?w=137> by 4 p.m. EST, July 31, 2018. Please feel free to share this information with other interested members of your organization or association.

Members of the public who are pre-registered to attend via webinar and later need to cancel, please do so by 9:00 a.m. EST on August 1, 2018 utilizing the following link: <https://teregistration.cbp.gov/cancel.asp?w=137>.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than 5:00 p.m. EST on July 31, 2018, and must be identified by Docket No. USCBP-2018-0026, and may be submitted by *one (1)* of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments.
- **Email:** [tradeevents@dhs.gov](mailto:tradeevents@dhs.gov). Include the docket number in the subject line of the message.
- **Fax:** (202) 325-4290, Attention Florence Constant-Gibson.
- **Mail:** Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.

**Instructions:** All submissions received must include the words "Department of Homeland Security" and the docket number (USCBP-2018-0026) for this action. Comments received will be posted without alteration at <https://www.regulations.gov>. Please do not submit personal information to this docket.

**Docket:** For access to the docket or to read background documents or comments, go to <https://www.regulations.gov> and search for Docket Number USCBP-2018-0026. To submit a comment, click the "Comment Now!" button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on August 1, 2018. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, <https://www.cbp.gov/trade/stakeholder-engagement/coac>.

**FOR FURTHER INFORMATION CONTACT:** Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; telephone (202) 344-1440; facsimile (202) 325-4290; or Mr. Bradley Hayes, Executive Director, Office of Trade Relations and Designated Federal Officer for COAC at (202) 344-1440.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

#### Agenda

The Designated Federal Officer will introduce the newly appointed, re-appointed, and alternate COAC members. The COAC will also hear from the following subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Exports Subcommittee will discuss a path forward for its work and the work of the Export Manifest Working Group for the 15th Term COAC. There will also be an update on the automated export manifest pilots, and on progress in implementing a post-departure filing pilot as part of the ocean pilot.
2. The Trusted Trader Subcommittee will present an update from the C-TPAT Minimum Security Criteria Working Group on its recommendation regarding CBP's plans to roll out new C-TPAT criteria. The subcommittee will also provide an update on the progress on the Trusted Trader Strategy and the formation of a new Trade Compliance Working Group.

3. The Trade Modernization Subcommittee will discuss the progress of the Regulatory Reform Working Group's efforts to identify and prioritize areas of regulations administered by CBP which can be reformed and the Foreign Trade Zone Regulations Working Group. In addition, the subcommittee will discuss the progress being made in the E-Commerce Working Group.

4. The Trade Enforcement and Revenue Collection (TERC) Subcommittee will provide updates from the Anti-Dumping/Countervailing Duties (AD/CVD), Bond, Forced Labor and Intellectual Property Rights Working Groups and will also speak to the lessons learned from the risk-based bonding tabletop exercise.

Meeting materials will be available by July 31, 2018 at: <http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings>.

Dated: July 11, 2018.

**Bradley F. Hayes,**  
Executive Director, Office of Trade Relations.  
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## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-7001-N-36]

### 30-Day Notice of Proposed Information Collection: Human Trafficking Housing Partnership

**AGENCY:** Office of the Chief Information Officer, HUD.

**ACTION:** Notice.

**SUMMARY:** HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

**DATES:** *Comments Due Date:* August 15, 2018.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202-395-5806, Email: [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:** Anna P. Guido, Reports Management