

**Guidance for Industry and FDA Staff—
Class II Special Controls Guidance
Document: Automated Blood Cell
Separator Device Operating by
Centrifugal or Filtration Separation
Principle**

OMB Control Number 0910-0594—
Extension

Under the Safe Medical Devices Act of 1990 (Pub. L. 101-629), FDA may establish special controls, including performance standards, postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device. The special control guidance serves as the special control for the automated blood cell separator device operating by centrifugal or filtration separation principle intended for the routine collection of blood and blood components (§ 864.9245 (21 CFR 864.9245)).

For currently marketed products not approved under the premarket approval process, the manufacturer should file with FDA for 3 consecutive years an annual report on the anniversary date of the device reclassification from class III to class II or on the anniversary date of the 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(k)) clearance. Any subsequent change to the device requiring the submission of a premarket notification in accordance with section 510(k) of the

FD&C Act should be included in the annual report. Also, a manufacturer of a device determined to be substantially equivalent to the centrifugal or filtration-based automated cell separator device intended for the routine collection of blood and blood components should comply with the same general and special controls.

The annual report should include, at a minimum, a summary of anticipated and unanticipated adverse events that have occurred and that are not required to be reported by manufacturers under Medical Device Reporting (MDR) (part 803 (21 CFR part 803)). The reporting of adverse device events summarized in an annual report will alert FDA to trends or clusters of events that might be a safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Reclassification of this device from class III to class II relieves manufacturers of the burden of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e) and may permit small potential competitors to enter the marketplace by reducing the burden. Although the special control guidance recommends that manufacturers of these devices file with FDA an annual report for 3 consecutive years, this would be less burdensome than the current postapproval requirements under 21

CFR part 814, subpart E, including the submission of periodic reports under 21 CFR 814.84.

Collecting or transfusing facilities, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collecting or transfusing facilities are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b))). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

In the special control guidance document, FDA recommends that manufacturers include in their three annual reports a summary of adverse reactions maintained by the collecting or transfusing facility or similar reports of adverse events collected.

In the **Federal Register** of February 22, 2018, (83 FR 7745), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not discussed here.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual Report	3	1	3	5	15

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

Based on FDA records, there are approximately three manufacturers of automated blood cell separator devices. We estimate that the manufacturers will spend approximately 5 hours preparing and submitting the annual report. The total burden hours are reduced from previous collections due to a decrease in the number of manufacturers.

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910-0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910-0437 (MDR, part 803).

Dated: July 9, 2018.
Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2018-15089 Filed 7-13-18; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Declaration Regarding Emergency Use of Treatment for Uncontrolled Hemorrhage Due to Agents of Military Combat

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to the Federal Food, Drug, and Cosmetic (FD&C) Act. On June 7, 2018, Patrick M. Shanahan, Deputy Secretary of Defense, determined in accordance with the Federal Food, Drug and Cosmetic Act, 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. 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.

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) Act¹ 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.

[FR Doc. 2018-15152 Filed 7-13-18; 8:45 am]

BILLING CODE 4150-37-P

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

¹ 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.”