deployed), folded, and transient positions.

5. The airplane must demonstrate acceptable handling qualities during rollout in a crosswind environment, as wingtips transition from the flight-deployed to folded position, as well as during the unlikely event of asymmetric wingtip folding.

6. The wingtip-fold operating mechanism must have stops that positively limit the range of motion of the wingtips. Each stop must be designed to the requirements of § 25.675.

7. The wingtip hinge structure must be designed for inertia loads acting parallel to the hinge line. In the absence of more rational data, the inertia loads may be assumed to be equal to KW as referenced in § 25.393. Hinge design must meet the requirements of § 25.657.

8. In lieu of § 25.1385(b): The forward position lights must be installed such that they consist of a red and a green light spaced laterally as far apart as practicable, and installed forward on the airplane, so that, with the airplane in the normal flying position and with the wingtips in the folded position for ground operations, the red light is on the left side and the green light is on the right side at approximately the level of the wingtips in the takeoff configuration. Each light must be approved and must meet the requirements of § 25.1385(a) and (d). The lights must not impair the vision of the flightcrew when the wingtips are in the folded and transient positions.

9. The applicant must include design features that ensure the wingtips are properly secured during ground operations, to protect ground personnel from bodily injury as well as to prevent damage to the airframe, ground structure, and ground support equipment.

10. The wingtips must have means to safeguard against unlocking from the extended, flight-deployed position in flight, as a result of failures, including the failure of any single structural element. All sources of airplane power that could initiate unlocking of the wingtips must be automatically isolated from the wingtip-fold operating system (including the latching and locking system) prior to flight, and it must not be possible to restore power to the system during flight. The wingtip latching and locking mechanisms must be designed so that, under all airplane flight-load conditions, no force or torque can unlatch or unlock the mechanisms. The latching system must include a means to secure the latches in the latched position, independent of the locking system. It must not be possible to position the lock in the locked position if the latches and the latching mechanisms are not in the latched position, and it must not be possible to unlatch the latches with the locks in the locked position.

Issued in Des Moines, Washington, on May 11, 2018.

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–10576 Filed 5–17–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2016–N–0406]

Medical Devices; Hematology and Pathology Devices; Classification of Blood Establishment Computer Software and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final rule to classify blood establishment computer software (BECS) and BECS accessories (regulated under product code MMH) into class II (special controls). FDA has identified special controls for BECS and BECS accessories that are necessary to provide a reasonable assurance of safety and effectiveness. FDA is also giving notice that the Agency does not intend to exempt BECS and BECS accessories from premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: This rule is effective June 18, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jessica Walker Udechukwu, 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:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

FDA is classifying BECS and BECS accessories into class II (special controls). The Agency believes that the special controls established and imposed by this final rule, together with the general controls, will provide reasonable assurance of the safety and effectiveness of these devices. In this final rule, FDA is also revising the definition of BECS accessories from the definition in the proposed rule and responding to comments received on the proposed rule. Lastly, FDA is giving notice that the Agency does not intend to exempt BECS and BECS accessories from the premarket notification requirements of the FD&C Act.

B. Summary of the Major Provisions of the Final Rule

In this final rule, FDA is classifying BECS and BECS accessories into class II (special controls). This rule creates § 864.9165 in 21 CFR part 864, subpart J, to include the identification and classification of BECS and BECS accessories. The classification of BECS and BECS accessories is consistent with the FDA Blood Product Advisory Committee (BPAC) recommendation that the devices be classified as class II (special controls) devices with premarket review.

C. Legal Authority

We are issuing this final rule under section 513(a)(1)(B) of the FD&C Act (21 U.S.C. 360c(a)(1)(B)). FDA has the authority under this provision of the FD&C Act to issue a regulation to establish special controls for class II

devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance. Under this authority, FDA is establishing special controls for BECS and BECS accessories.

D. Costs and Benefits

FDA is finalizing this regulation to classify BECS and BES accessories into class II (special controls). Because this final rule would not impose significant new obligations on manufacturers, this regulation is not anticipated to result in any significant new compliance costs and the economic impact is expected to be minimal.

II. Background

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (1976 Amendments), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act establishes three categories (classes) of devices depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Class I devices are those devices for which the general controls of the FD&C Act (controls authorized by or under sections 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness of the device. Class I also includes those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act). Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act). Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness, and are purported or represented for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation, along with a proposed regulation classifying the device, and provides an opportunity for interested persons to submit comments; and (3) publishes a final regulation classifying the device.

FDA has classified most preamendments devices under these procedures, relying upon valid scientific evidence as described in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c), to determine that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use.

Devices that were not in commercial distribution before May 28, 1976 (generally referred to as ''postamendments devices''), are classified automatically by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) FDA classifies or reclassifies the device into class I or II or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval.

The Agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

A. Need for the Regulation/History of This Rulemaking

After the enactment of the 1976 amendments, FDA began to identify and classify all preamendments devices in accordance with section 513(b) of the FD&C Act. BECS and BECS accessories are preamendments devices. The first BECS 510(k) premarket notification was cleared by FDA on August 26, 1996. Information Data Management, Inc., submitted premarket notifications for their Components & Distribution Information System and Donor Management Information System. These devices were compared to systems marketed prior to the 1976 amendments, including the Blood Inventory Management System by Computer Sciences Corp. and the Donor Deferral Registry developed by the American National Red Cross. Between 1996 and the time FDA drafted the proposed rule in December 2015, FDA had cleared 220 BECS and BECS accessories under the 510(k) program. BECS and BECS accessories are regulated under product code MMH.

In 1998, FDA sought recommendations from the BPAC, serving as a Device Classification Panel, on the classification of BECS. The Device Classification Panel recommended regulating BECS as a class II device with premarket review (Ref. 1). The classification of BECS was not finalized following the Device Classification Panel's recommendation in 1998 because of competing priorities.

On December 3, 2014, the BPAC, serving as a Device Classification Panel (the Panel), again convened to discuss the classification of BECS and BECS accessories (Ref. 2). The Panel discussed the risks to health associated with BECS and BECS accessories, the classification of BECS and BECS accessories, and, if classified as class II devices, the special controls that would be required for these devices. The Panel agreed that general controls were not sufficient to provide a reasonable assurance of safety and effectiveness of BECS and BECS accessories. The Panel believed that BECS and BECS accessories presented a potential unreasonable risk of illness, injury, or death, and that sufficient information exists to establish special controls for these devices.

Consequently, the Panel recommended that these devices be classified into class II (special controls) with premarket review.

After considering the recommendations of the Panel and the valid scientific evidence, including the published literature, medical device reports, recall information, and FDA's extensive inspection and regulatory experiences with these device types (Ref. 3), FDA published a proposed rule in the **Federal Register** of March 1, 2016 (81 FR 10553), to classify BECS and BECS accessories into class II (special controls) with premarket review. In the proposed rule, FDA identified the risks to health and the mitigation measures for BECS and BECS accessories. FDA assessed the risks to health for BECS accessories and found these risks to be the same as BECS and, therefore, proposed to classify the BECS as the parent device and BECS accessories together. FDA is not aware of any new information that has arisen since this Panel meeting and the publication of the proposed rule that would provide a basis for different recommendations or findings. FDA believes general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness for these devices and that there is sufficient information to establish special controls to provide such assurance. FDA believes that special controls, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of BECS and BECS accessories and would, therefore, mitigate risks as summarized in table 1.

TABLE 1—HEALTH RISKS AND MITIGATION MEASURES FOR BECS AND BECS ACCESSORIES

Identified risks to health	Mitigation measures
Transfusion reaction or death	Performance and functional requirements.
Transmission of infectious disease	Performance and testing.
Donor health risk from too frequent or inappropriate donation	Labeling.

The special controls that were proposed for BECS and BECS accessories—specifically performance and functional requirements, device verification and validation, hazard analysis, traceability matrix, performance testing, and labeling—collectively ensure that the manufacturer performs and documents the activities necessary to decrease the risk of malfunction that could result in adverse events. Further, appropriate labeling ensures that the user of the device is provided clear instructions for use, including the limitations of the device, to reduce the risk of user error that could result in the risks to health associated with these devices.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. The Agency does not intend to exempt BECS and BECS accessories from 510(k) premarket notification as allowed under section 510(m) of the FD&C Act. FDA believes premarket notification is necessary for these devices to assure their safety and effectiveness.

B. Summary of Comments to the Proposed Rule

Most of the comments expressed support for the proposed rule and agreed with the proposed classification of BECS and BECS accessories as class II devices and the proposed special controls. Two commenters disagreed with the proposed classification of BECS and BECS accessories into class II. Several comments requested clarification of the definition of BECS accessory. Several commenters requested clarification on the proposed special controls.

III. Legal Authority

We are issuing this final rule under section 513(a)(1)(B) of the FD&C Act. FDA has the authority under this provision of the FD&C Act to issue a regulation to establish special controls for class II devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Under this authority, FDA is establishing special controls for the class II devices for BECS and BECS accessories.

IV. Comments on the Proposed Rule and FDA Response

A. Introduction

In response to the proposed rule (81 FR 10553) to classify BECS and BECS accessories into class II, we received seven comment letters by the close of the comment period, each containing one or more comments on one or more issues. We received comments from a blood establishment, two trade organizations representing the blood and plasma industries, one device manufacturer, one anonymous response, one private citizen, and one public health research organization.

We describe and respond to the comments in section IV.B. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Specific Comments and FDA Response

(Comment 1) One comment suggested that FDA has failed to establish that BECS and BECS accessories present an ''unreasonable'' risk of illness or injury.

(Response 1) We disagree. As presented to the Panel on December 3, 2014, in the 1990s during establishment inspection observations, it was revealed that unsuitable blood and blood components had been released and distributed as a result of improperly designed software. This posed potential unreasonable risks to health such as transfusion reaction, injury or death, and transmission of infectious disease. These observations resulted in warning letters and recalls of the unsuitable blood and blood components, as well as warning letters and recalls of the defective software. Furthermore, as BECS programs became increasingly complex, FDA investigators found that validation solely by the end user of the device was proving impractical, and was insufficient to assure software performance. Therefore, FDA determined that there were potential unreasonable risks to health associated with BECS and convened the Panel in December 2014. The Panel considered the scientific evidence presented at the meeting and recommended that BECS and BECS accessories be classified into

class II (special controls) with premarket review. After considering the recommendations of the Panel and the valid scientific evidence, including the published literature, medical device reports, recall information, and FDA's extensive inspection and regulatory experiences with these device types (Ref. 3), FDA proposed that BECS and BECS accessories be classified into class II (special controls) with premarket review. In the proposed rule, FDA proposed that special controls, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of BECS and BECS accessories and would, therefore, mitigate the risks to patients of transfusion reaction or death and transmission of infectious disease and risks to donors because of inappropriate donations. FDA is not aware of any new information that has arisen since this Panel meeting and the publication of the proposed rule that would provide a basis for different recommendations or findings. Accordingly, this final rule classifies BECS and BECS accessories into class II (special controls) with premarket review.

(Comment 2) One comment recommended that the rule should detail the requirements for verification and validation.

(Response 2) The final rule includes verification and validation testing as a special control. FDA issued the guidance entitled ''General Principles of Software Validation; Final Guidance for Industry and FDA Staff'' on January 11, 2002, which outlines general validation principles and recommendations that are considered applicable to the validation of medical device software, or the validation of software used to design, develop, or manufacture medical devices (Ref. 4). BECS manufacturers can follow the recommendations in this guidance to help ensure appropriate validation testing of their device. FDA believes that the recommendations in this guidance support the requirements in the Quality System Regulation (21 CFR part 820), and can assist manufacturers in meeting the requirements for verification and validation testing as a special control.

(Comment 3) Multiple comments requested clarification of the definition of BECS accessories.

(Response 3) FDA agrees that clarification of BECS accessories is needed. To provide greater clarity we have revised the identification language in the classification regulation. Under the final rule, a BECS accessory is defined as a device intended for use with BECS to augment its performance or to expand or modify its indications for use. In response to comments, we are providing examples of BECS accessories.

The following examples are BECS accessories:

- A software device that queries a BECS to find blood components and donors that meet specific requirements, *e.g.,* Human Leukocyte Antigen and Cytomegalovirus status and allows the selections of the most suitable blood component for the recipient and, in doing so, expands the indications for use of the BECS.
- A software device that augments the performance and expands the indications for use of the BECS by providing biometric technology to identify a blood donor.
- A software device that augments the performance of the BECS by providing algorithms for donor or transfusion management.

The following examples are not BECS accessories:

- An interface that merely transmits data from an external device to the BECS such as billing information or inventory information to stock units in the blood bank is not a BECS accessory. These functionalities are not related to the indications for use of a BECS and do not alter the data of the BECS; thus, such an interface would not meet the definition of a BECS accessory.
- An interface from a blood pressure device to the BECS that performs a straight transfer of blood pressure information but does not modify the medical data before or during the transfer is not a BECS accessory. The data transfer itself does not expand the indications for use of the BECS; it merely transfers data without manipulation of the data or addition of logic function. Thus, it would not meet the definition of a BECS accessory.
- An interface between two BECS systems that is a straight transfer of information and where the interface software does not modify the medical data before or during the transfer does not meet the definition of a BECS accessory because it is not used to augment the performance of the BECS or to expand or modify its indications for use.
- An interface that merely transfers data from the BECS to another device simply for donor appointments is not a BECS accessory. It does not meet the definition of a BECS accessory because it is not used to augment the performance of the BECS or to expand or modify its indications for use (it is simply transferring data from the BECS).

(Comment 4) One comment recommended that we distinguish a BECS accessory from Medical Device Data Systems (MDDS).

(Response 4) A BECS accessory is a device used with BECS to augment the performance or expand or modify the indications for use of the BECS. Like BECS, BECS accessories are not MDDS because they are intended to do more than simply transfer, store, or display medical device data or convert medical device data from one format to another format in accordance with a preset specification.

Section 3060 of the 21st Century Cures Act (Cures Act), Pub. L. 114–255 (2016), amended the FD&C Act to add section 520(*o*) (21 U.S.C. 360j(*o*)), which describes certain software functions, including functions performed by MDDS, that are excluded from the definition of device in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). Section 3060 of the Cures Act further states that section 520(*o*) of the FD&C Act shall not be construed to limit FDA's authority to regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans. Therefore, BECS and BECS accessories are not covered by section 520(*o*)(1)(D) of the FD&C Act, and FDA regulates BECS and BECS accessories as devices.

(Comment 5) One comment asked if software intended for the maintenance of data that blood establishments use in making decisions regarding the suitability of donors and the release of blood components for transfusion or further manufacture would be classified as BECS.

(Response 5) Software that uses the stored data for the purposes of identifying ineligible donors, preventing the release of unsuitable blood and blood components for transfusion or for further manufacture, performing compatibility testing between donor and recipient, or performing positive identification of patients and blood components at the point of transfusion would meet the definition of BECS. Software intended for electronic storage of medical data without interpreting or analyzing the data or altering the functions or parameters of any connected medical device would not meet the definition of BECS.

(Comment 6) One comment stated that the definition of BECS does not cover middleware applications used to send data from a device used in blood collection centers to a Donor Management System and asked for clarification regarding the regulation of such products.

(Response 6) Middleware applications that only transfer medical data from one medical device to another medical

device and do not augment the performance or expand or modify the indications for use of the BECS would not meet the definition of a BECS accessory.

(Comment 7) One comment questioned whether beta testing should be included as a special control.

(Response 7) The final regulation includes verification and validation testing as a special control. Verification and validation testing should include beta testing which can be performed in a user environment or simulated user environment.

The guidance document entitled ''General Principles of Software Validation; Final Guidance for Industry and FDA Staff'' issued January 11, 2002 (Ref. 4), provides recommendations on software validation.

(Comment 8) One comment asked FDA to clarify its expectations with respect to the development and presentation of a traceability matrix.

(Comment 8) FDA has provided recommendations for developing a traceability matrix in the document entitled, ''Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,'' issued May 11, 2005 (Ref. 5).

(Comment 9) One comment recommended we review BECS and BECS accessories through the PMA (class III) approval process since there have been injuries and deaths associated with these devices. The comment also stated that there is not sufficient information to establish class II special controls for the devices.

(Response 9) Although BECS and BECS accessories are currently unclassified, FDA has regulated these devices for more than 20 years, and during this time period, FDA has applied standards for class II devices in reviewing 510(k)s for these devices. No deaths or serious injuries have been attributed to the malfunction of the device. As described in FDA's Executive Summary to the BPAC meeting of December 3, 2014 (Ref. 3), valid scientific evidence, including the published literature, medical device reports, recall information, and FDA's extensive inspection and regulatory experiences with these device types, supports classifying BECS and BECS accessories into Class II with special controls. After considering this evidence, the Panel recommended classification of BECS and BECS accessories as a Class II device with special controls. After considering the recommendations of the Panel and the valid scientific evidence, FDA proposed that BECS and BECS accessories be classified into class II (special controls) with premarket review. In the proposed rule, FDA proposed that special controls, in addition to general controls, would provide a reasonable assurance of the safety and effectiveness of BECS and BECS accessories and would, therefore, mitigate the risks to patients of transfusion reaction or death and transmission of infectious disease and risks to donors because of inappropriate donations. FDA is not aware of any new information that has arisen since this Panel meeting and the publication of the proposed rule that would provide a basis for different recommendations or findings. Accordingly, this final rule classifies BECS and BECS accessories into class II (special controls) with premarket review. For additional information on premarket submissions, please refer to the following guidance documents: ''Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,'' issued May 11, 2005 (Ref. 5), and ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and FDA Staff,'' issued October 25, 2017 (Ref. 6).

(Comment 10) One comment stated that the proposed rule lacked a cost/benefit discussion on the proposed classification.

(Response 10) Sections I.D. and VI. of this rule discusses FDA's economic analysis of impacts of the final rule. As discussed in the proposed rule and in sections I.D. and VI. of this final rule, under current practice, manufacturers already conform to the special controls for BECS and BECS accessories. This rule would essentially formalize current practice, and will not result in any additional associated costs or benefits.

(Comment 11) One comment stated that the Center for Devices and Radiological Health in FDA has identified Sanguin Medusa 2000 with the product code MMH; and it is listed as being cleared September 29, 1994, which predates the first FDA cleared 510(k) for BECS identified in the proposed rule.

(Response 11) While this comment is outside the scope of the proposed rule, we appreciate the comment and will ensure that proper product codes are assigned to this product, which is not a BECS or BECS accessory.

V. Effective Date

This final rule will become effective 30 days after its publication in the **Federal Register**.

VI. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the costs associated with significant new regulations ''shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule is consistent with historical regulatory oversight given to this type of device, and would not impose any additional regulatory burdens, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule classifies BECS and BECS accessories into class II devices with special controls and subject to premarket review. The special controls for these devices are necessary to provide a reasonable assurance of safety and effectiveness. Between 1996 and the time that FDA drafted the proposed rule in December 2015, FDA had cleared 220 BECS and BECS accessories under the 510(k) program, consistent with the recommendations in the FDA guidance, ''Guidance for Industry and FDA Staff;

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,'' issued May 11, 2005 (Ref. 5). As current practice, manufacturers already conform to the recommended controls for BECS and BECS accessories. This rule would essentially formalize current practice and will not result in any additional associated costs. Likewise, this classification will not result in any significant changes in how premarket notifications for the affected devices are submitted or prepared by manufacturers or in how they are reviewed by FDA. Therefore, compliance with the special controls for this device would not yield significant new costs for affected manufacturers. Because the classification of these devices to class II (special controls) would not impose significant new obligations on manufacturers, the Agency concludes that the rule will impose no additional regulatory burdens.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This final rule refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

IX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XI. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Blood Products Advisory Committee Meeting transcript, March 20, 1998 (*http://www.fda.gov/ohrms/dockets/ac/98/transcpt/3391t2.pdf).*
2. Blood Products Advisory Committee Meeting transcript, December 3, 2014 (*https://wayback.archive-it.org/7993/20170111180042/http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm386681.htm).*
3. FDA Executive Summary. Blood Products Advisory Committee Meeting, December 3, 2014 (*https://wayback.archive-it.org/7993/20170111180042/ http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm386681.htm).*
4. General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002 (*https://www.fda.gov/downloads/MedicalDevices/.../ucm085371.pdf*).
5. Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm089593.pdf*).
6. Deciding When to Submit a 510(k) for a Software Change to an Existing Device: Guidance for Industry and FDA Staff, October 25, 2017 (*https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514737.pdf*).

List of Subjects in 21 CFR Part 864

Blood, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 864 is amended as follows:

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 1. The authority citation for part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 2. Add § 864.9165 to subpart J to read as follows:

§ 864.9165 Blood establishment computer software and accessories.

(a) *Identification.* Blood establishment computer software (BECS) is a device used in the manufacture of blood and blood components to assist in the prevention of disease in humans by identifying ineligible donors, by preventing the release of unsuitable blood and blood components for transfusion or for further manufacturing into products for human treatment or diagnosis, by performing compatibility testing between donor and recipient, or by performing positive identification of patients and blood components at the point of transfusion to prevent transfusion reactions. This generic type of device may include a BECS accessory, a device intended for use with BECS to augment the performance of the BECS or to expand or modify its indications for use.

(b) *Classification.* Class II (special controls). The special controls for these devices are:

(1) Software performance and functional requirements including detailed design specifications (*e.g.,* algorithms or control characteristics, alarms, device limitations, and safety requirements).

(2) Verification and validation testing and hazard analysis must be performed.

(3) Labeling must include:

(i) Software limitations;

(ii) Unresolved anomalies, annotated with an explanation of the impact on safety or effectiveness;

(iii) Revision history; and

(iv) Hardware and peripheral specifications.

(4) Traceability matrix must be performed.

(5) Performance testing to ensure the safety and effectiveness of the system must be performed, including when adding new functional requirements (*e.g.,* electrical safety, electromagnetic compatibility, or wireless coexistence).

Dated: May 14, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10610 Filed 5–17–18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket Number USCG–2018–0320]

RIN 1625–AA08

Special Local Regulation; Monongahela, Allegheny, and Ohio Rivers, Pittsburgh Pennsylvania

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation for parts of the navigable waters of the Allegheny, Monongahela, and Ohio Rivers. This action is necessary to ensure safety of life on these navigable waters during the weekend of the Luke Bryan concert at Heinz Field. Persons and vessels are prohibited from loitering, anchoring, stopping, mooring, remaining, or drifting in any manner that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative. In addition, persons and vessels are prohibited from loitering, anchoring, stopping, or drifting more than 100 feet from any riverbank unless authorized by the Captain of the Port Marine Safety Unit Pittsburgh or a designated representative.

DATES: This rule is effective from 4 p.m. on June 29, 2018 through noon on July 1, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2018–0320 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Petty Officer Jennifer Haggins, Marine Safety Unit Pittsburgh Waterways Division, U.S. Coast Guard; telephone 412–221–0807, email *Jennifer.L.Haggins@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Marine Safety Unit Pittsburgh
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

Heinz Field has notified the Coast Guard that it would be holding a concert from 4 p.m. to 11 p.m. on June 30, 2018. Heinz Field is located in close proximity to the banks of the Ohio and Allegheny Rivers, which are high vessel traffic areas used by both commercial and recreational vessels. Due to the proximity of Heinz Field to these waterways, it will be a destination for many recreational vessels that will anchor and loiter throughout the concert weekend of June 29, 2018 to July 1, 2018. In response, on April 17, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled Special Local Regulation; Monongahela (MM 0.22), Allegheny (MM 0.8), and Ohio Rivers (0.8), Pittsburgh, PA (83 FR 16808). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this concert. During the comment period that ended May 2, 2018, we received no comments.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety concerns and hazards that could occur in this area during the concert.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The Captain of the Port Marine Safety Unit Pittsburgh (COTP) has determined that this special local regulation is necessary to maintain an open navigation channel and ensure the safety of vessels on these navigable waters during the concert weekend. The Coast Guard is concerned about possible collisions that could occur in this area and the impact of vessel congestion on maritime commerce due to transit delays. The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters adjacent to Heinz Field, the Allegheny, Monongahela, and Ohio Rivers before, during, and after the Luke Bryan concert weekend.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received no comments on our NPRM published April 17, 2018. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

This rule establishes a special local regulation from 4 p.m. on June 29, 2018 through noon on July 1, 2018. The special local regulation covers all navigable waters of the Allegheny, Monongahela, and Ohio Rivers between the Ninth Street Highway Bridge at mile marker (MM) 0.8, Allegheny River, Fort Pitt Highway Bridge at MM 0.22, Monongahela River, and West End-North Side Highway Bridge at MM 0.8, Ohio River. The duration of the zone is intended to ensure the safety of vessels on these navigable waters during the concert weekend. This special local regulation applies to any vessel operating within the area, including a naval or public vessel, except a vessel engaged in law enforcement, servicing aids to navigation, or surveying, maintaining, or improving waters within the regulated area. No vessel is permitted to loiter, anchor, stop, moor, remain or drift in any manner that impedes safe passage of another vessel to any launching ramp, marina, or fleeting area unless authorized by the COTP or a designated representative. In addition, no vessel or person is permitted to loiter, anchor, stop, remain, or drift more than 100 feet from any riverbank unless authorized by the COTP or a designated representative. Persons and vessels seeking entry into the regulated area must request permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Marine Safety Unit Pittsburgh. They may be contacted on VHF–FM Channel 16. Persons and vessels permitted to enter this regulated area must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and