individuals who had contact with Ebola patients.

Transmission of Ebola virus from human to human occurs by direct contact with body fluids (such as blood, urine, stool, saliva, semen, vaginal fluids, or vomit) of symptomatic infected individuals. Therefore, blood and blood products from symptomatic individuals, if they were to donate, would have the potential of transmitting Ebola virus to recipients.

Current regulations 21 CFR 640.3(b) and 21 CFR 640.63(b)(3) require that a donor be in good health with a normal temperature at the time of donation. Standard procedures that are in place to assure that the donor feels healthy at the time of donation serve as an effective safeguard against collecting blood or blood components from a donor who seeks to donate after the onset of clinical symptoms. FDA is providing guidance to reduce the risks of collecting blood and blood components from potentially Ebola virus-infected persons during the asymptomatic incubation period before the onset of clinical symptoms, as well as from individuals with a history of Ebola virus infection or disease.

The draft guidance permits blood establishments to update their donor educational materials to instruct donors with a history of Ebola virus infection or disease to not donate blood or blood components. In the event that one or more countries is designated as having widespread transmission of Ebola virus, the draft guidance includes recommendations to blood establishments to update their donor history questionnaire (DHQ), including the full-length and abbreviated DHQ and accompanying materials, to assess prospective donors for risk of Ebola virus infection or disease. The draft guidance also includes recommendations to blood establishments to defer indefinitely a blood donor with a history of Ebola virus infection or disease, until more data regarding the persistence of Ebola virus in survivors becomes available. For a donor who in the past 8 weeks has been a resident of or has travelled to a country with widespread transmission of Ebola virus disease, FDA recommends that establishments defer the donor for 8 weeks from the time of the donor's departure from that country. For a donor who has had close contact with a person confirmed or under investigation for Ebola virus infection or disease in whom diagnosis is pending, FDA recommends that establishments defer a donor for 8 weeks after the last close contact that could have resulted in direct contact with body fluids, or 8 weeks after the last sexual contact with a person known to have recovered from Ebola virus disease. In addition, FDA recommends that establishments defer for a period of 8 weeks after exposure a donor who has been notified by a Federal, State, or local public health authority that he or she may have been exposed to a person with Ebola virus disease.

The draft guidance includes FDA recommendations on retrieval and quarantine of blood and blood components from a donor later determined to have Ebola virus infection or disease or risk factors for Ebola virus infection or disease, for notification of consignees, and for reporting a biological product deviation to FDA. The draft guidance also addresses convalescent plasma intended for transfusion.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 606.160(b)(1)(i), 640.3(a) and 640.63(b)(3) have been approved under OMB control number 0910–0116; the collection of information in 21 CFR 606.171 has been approved under OMB control number 0910–0458.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–30589 Filed 12–2–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0017]

Agency Information Collection Activities: Protest

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Protest. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before February 1, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Protest.

OMB Number: 1651–0017.

Form Number: Form 19.

Abstract: CBP Form 19, *Protest,* is filed to seek the review of a CBP officer. This review may be conducted by a CBP officer who participated directly in the underlying decision. This form is also used to request ''Further Review'' which means a request for review of the protest to be performed by a CBP officer who did not participate directly in the protested decision, or by the Commissioner, or his designee as provided in the CBP Regulations.

The matters that may be protested include: The appraised value of merchandise; the classification and rate and amount of duties chargeable; all charges within the jurisdiction of the U.S. Department of Homeland Security; exclusion of merchandise from entry or delivery, or demand for redelivery; the liquidation or reliquidation of an entry; and the refusal to pay a claim for drawback.

The parties who may file a protest or application for further review include: the importer or consignee shown on the entry papers, or their sureties; any person paying any charge or exaction; any person seeking entry or delivery, or upon whom a demand for redelivery has been made; any person filing a claim for drawback; or any authorized agent of any of the persons described above.

CBP Form 19 collects information such as the name and address of the protesting party, information about the entry being protested, detailed reasons for the protest, justification for applying for further review.

The information collected on CBP Form 19 is authorized by Sections 514 and 514(a) of the Tariff Act of 1930 and provided for by 19 CFR part 174. This form is accessible at *http://www.cbp.gov/sites/default/files/documents/CBP_Form_19.pdf.*

Current Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information collected.

Type of Review: Extension (with no change).

Affected Public: Businesses.

Estimated Number of Respondents: 3,750.

Estimated Number of Total Annual Responses: 45,000.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 45,000.

Dated: November 30, 2015.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015–30614 Filed 12–2–15; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0052]

Agency Information Collection Activities: User Fees

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: User Fees. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before February 1, 2016 to be assured of consideration.

ADDRESSES: Written comments may be mailed to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: User Fees.

OMB Number: 1651–0052.

Form Number: CBP Forms 339A, 339C and 339V.

Abstract: The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA—Pub. L. 99–272; 19 U.S.C. 58c) authorizes the collection of user fees by Customs and Border Protection (CBP). The collection of these fees requires submission of information from the party remitting the fees to CBP. This information is submitted on three forms including the CBP Form 339A for aircraft at: *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%20339A.pdf,* CBP Form 339C for commercial vehicles at: *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%20339C.pdf,* and CBP Form 339V for vessels at: *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%20339V.pdf.* The information on these forms may also be filed electronically at: *https://dtops.cbp.dhs.gov/.* This collection of information is provided for by 19 CFR 24.22.

In addition, CBP requires express consignment courier facilities (ECCFs) to file lists of couriers using the facility in accordance with 19 CFR 128.11. In cases of overpayments, carriers using the courier facilities may send a request