control number 0938–0685; the CMS–855S is approved under OMB control number 0938–1056.

IV. Regulatory Impact Statement

A. Background

We have examined the impact of this notice as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As explained in this section of the notice, we estimate that the total cost of the increase in the application fee will not exceed $100 million. Therefore, this notice does not reach the $100 million economic threshold and is not considered a major notice.

B. Costs

The costs associated with this notice involve the increase in the application fee amount that certain providers and suppliers must pay in CY 2016.

1. Estimates of Number of Affected Institutional Providers in December 5, 2014 Fee Notice

In the December 5, 2014 application fee notice, we estimated that based on CMS statistics—

- 10,000 newly enrolling Medicare institutional providers would be subject to and pay an application fee in CY 2015.
- 35,000 revalidating Medicare institutional providers would be subject to and pay an application fee in CY 2015.
- 8,438 newly enrolling Medicaid and CHIP providers would be subject to and pay an application fee in CY 2015.
- 19,421 revalidating Medicaid and CHIP providers would be subject to and pay an application fee in CY 2015.

2. CY 2016 Estimates

a. Medicare

Based on CMS data, we estimate that in CY 2016 approximately—

- 10,000 newly enrolling institutional providers will be subject to and pay an application fee; and
- 45,000 revalidating institutional providers will be subject to and pay an application fee.

Using a figure of 55,000 (10,000 newly enrolling + 45,000 revalidating) institutional providers, we estimate an increase in the cost of the Medicare application fee requirement in CY 2016 of $5,585,000 (or (10,000 additional newly enrolling or revalidating institutional providers × $554) + (45,000 × $1.00) from our CY 2015 projections and as previously described.

b. Medicaid and CHIP

Based on CMS and state statistics, we estimate that approximately 30,000 (9,000 newly enrolling + 21,000 revalidating) Medicaid and CHIP institutional providers will be subject to an application fee in CY 2016. Using this figure, we project an increase in the cost of the Medicaid and CHIP application fee requirement in CY 2016 of $1,213,973 (or ((562 additional newly enrolling institutional providers + 1,579 additional revalidating institutional providers, or 2,141 total additional institutional providers) × $554) + 27,859 × $1.00) from our CY 2015 projections and as previously described.

c. Total

Based on the foregoing, we estimate the total increase in the cost of the application fee requirement for Medicare, Medicaid, and CHIP providers and suppliers in CY 2016 to be $6,798,973 ($5,585,000 + $1,213,973) from our CY 2015 projections.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. As we stated in the RIA for the February 2, 2011 final rule with comment period (76 FR 5952), we do not believe that the application fee will have a significant impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. The Agency has determined that there will be minimal impact from the costs of this notice, as the threshold is not met under the UMRA.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this notice does not impose substantial direct costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

Dated: November 14, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–30686 Filed 12–2–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2175]

Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled ''Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry.'' The draft guidance document provides blood establishments that collect blood and blood components for transfusion or further manufacture, including Source Plasma, with FDA recommendations for assessing blood donor suitability, donor deferral, and blood product management in the event that an outbreak of Ebola virus disease (EVD) with widespread transmission is declared in at least one country. The draft guidance document applies primarily to Ebola virus (species *Zaire ebolavirus*), but recommendations are expected to apply to other viruses of the Ebolavirus genus such as Sudan virus, Bundibugyo virus, and Taï Forest virus. The recommendations would apply to routine collection of blood and blood components for transfusion or further manufacture, including Source Plasma.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 2, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA 2014–D–2175 for ''Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., 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:

I. Background

FDA is announcing the availability of a draft document entitled ''Recommendations for Assessment of Blood Donor Suitability, Donor Deferral and Blood Product Management in Response to Ebola Virus; Draft Guidance for Industry.'' The draft guidance document provides blood establishments that collect blood and blood components for transfusion or further manufacture, including Source Plasma, with FDA recommendations for assessing blood donor suitability, donor deferral, and blood product management in the event that an outbreak of EVD with widespread transmission is declared in at least one country.

Ebola virus is a member of the family *Filoviridae* that can cause severe hemorrhagic fever in humans and non-human primates with historically high morbidity and mortality rates of up to 90 percent. However, in the 2014 outbreak in West Africa, the mortality rate has been markedly lower. In humans, EVD is typically characterized at onset by fever, severe headache, muscle pain and weakness, followed by diarrhea, vomiting, abdominal pain, and sometimes diffuse hemorrhage (bleeding or bruising). In previous outbreaks of EVD, symptoms generally appeared within 21 days and most often within 4–10 days following infection; however, based on mathematical models, symptom onset later than 21 days is estimated as possible in 0.1 to 12 percent of cases. In addition, there have been isolated reports of apparently asymptomatic Ebola virus infection in

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