TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Guidance document provision	Number of respondents	Number of responses per respondent	Total one-time responses	Average burden per response (in hours)	Total hours
Initial VQIP application	100	1	100	80	8,000
Initial VQIP application with re-submissions	100	1	100	100	10,000
Total One-Time Reporting Burden					18,000

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance document provision	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Renewal of VQIP application	200	1	200	20	4,000
Total Annual Reporting Burden					4,000

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

The draft guidance document allows for food importers to apply for VQIP. We estimate that up to 200 qualified importers will be accepted in the first year of VQIP. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for the VQIP program. For the purpose of this analysis, we assume that 50 percent of all applications received will require additional information and it would take an additional 20 person-hours by the importer to provide that information. Therefore, we estimate that 100 importers will spend 8,000 hours (80 hours/importer × 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer × 100 importers) to submit their initial VQIP applications for a total one-time reporting burden of 18,000 hours (see table 3).

The draft guidance document states that each VQIP participant will submit to FDA a notice of intent to maintain its participation in VQIP and update information on its original application on an annual basis. We expect that each of the expected 200 importers in VQIP would apply to renew their intent to maintain their participation in VQIP. We expect that annual applications to renew participation in VQIP will take significantly less time to prepare than initial applications. We use 25 percent of the amount of effort to prepare and submit the initial application for acceptance in VQIP. Therefore, it is expected that, on average, each VQIP importer will spend 20 hours every year to complete and submit an application for renewal of its VQIP status. The annual burden of completing the renewal application for VQIP status by 200 importers is estimated at 4,000 hours (200 applications × 20 hours/application) (see table 4). For the purposes of the PRA analysis of the draft guidance document, we have estimated costs assuming that, during the annual application process, affected importers will do their paperwork properly and completely the first time. Because we assume that importers will have learned about supporting documentation they need to submit during the initial application process, we have not estimated an additional burden for less than complete annual applications. If we assumed a less consistent outcome, the annual burden might be slightly higher.

IV. Comments

Interested persons may submit either electronic comments regarding this draft guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

Persons with access to the Internet may obtain this draft guidance at either *http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

VI. References

1. U.S. Food and Drug Administration. Proposed Analysis of Economic Impacts—Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, available under Docket No. FDA–2011–N–0920.
2. U.S. Food and Drug Administration. Focused Mitigation Strategies to Protect Food Against Intentional Adulteration (78 FR 78014, December 24, 2013).

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13706 Filed 6–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0126]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Ebola Virus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations), one of which was amended after initial issuance, for in vitro diagnostic devices for detection of the Ebola virus in response to the Ebola virus outbreak in West Africa. FDA

issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Corgenix, Inc. (Corgenix), and Cepheid. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow the September 22, 2006, determination by then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, that the Ebola virus presents a material threat against the U.S. population sufficient to affect national security. On the basis of such determination, the Secretary of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus subject to the terms of any authorization issued under the FD&C Act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for the Corgenix ReEBOV™ Antigen Rapid Test is effective as of February 24, 2015, and was amended and reissued on March 16, 2015. The Authorization for the Cepheid Xpert® Ebola Assay is effective as of March 23, 2015.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Carmen Maher, Acting Assistant Commissioner for Counterterrorism Policy and Acting Director, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (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 agent or agents; (2) 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 U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS 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 U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service Act (PHS Act) (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [1] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

II. EUA Requests for In Vitro Diagnostic Devices for Detection of the Ebola Virus

On September 22, 2006, then-Secretary of Homeland Security, Michael Chertoff, determined that the

[1] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

Ebola virus presents a material threat against the U.S. population sufficient to affect national security.[2] On August 5, 2014, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the **Federal Register** on August 12, 2014 (79 FR 47141). On February 22, 2015, Corgenix submitted a complete request for, and on February 24, 2015, FDA issued, an EUA for the ReEBOV™ Antigen Rapid Test, subject to the terms of the Authorization. On March 16, 2015, in response to a request from Corgenix on March 10, 2015, FDA amended and reissued in its entirety the EUA to allow, in addition to Corgenix, distributors that are authorized by Corgenix to distribute the ReEBOV™ Antigen Rapid Test, with certain conditions applicable to such authorized distributor(s), subject to the terms of this Authorization. This EUA, as amended and reissued on March 16, 2015, which includes an explanation for its reissuance, is reprinted in this document. Because the March 16, 2015, Authorization for Corgenix's assay replaces in its entirety the EUA issued on February 24, 2015, the original Authorization issued on February 24, 2015, is not reprinted in this document. On February 26, 2015, Cepheid submitted a complete request for, and on March 23, 2015, FDA issued, an EUA for the Xpert® Ebola Assay, subject to the terms of this Authorization.

[2] Under section 564(b)(1) of the FD&C Act, the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat under section 319F–2 of the PHS Act sufficient to affect national security or the health and security of U.S. citizens living abroad (section 564(b)(1)(D) of the FD&C Act).

III. Electronic Access

Electronic versions of these documents and the full text of the Authorizations are available on the Internet at *http://www.regulations.gov.*

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of in vitro diagnostic devices for detection of the Ebola virus subject to the terms of the Authorizations. The Authorization for the Corgenix ReEBOV™ Antigen Rapid Test issued on March 16, 2015, in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 16, 2015

Daniel F. Simpson, RAC (U.S., CAN), ASQ CBA
Sr. Director of Quality and Regulatory Affairs
Corgenix Inc.
11575 Main Street, Suite 400
Broomfield, CO 80020

Dear Mr. Simpson:

On February 24, 2015, based on a request by Corgenix Inc., the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola viruses[1] in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection), pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). The authorized ReEBOV™ Antigen Rapid Test is intended for circumstances when use of a rapid Ebola virus test is determined to be more appropriate than use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The authorized ReEBOV™ Antigen Rapid Test is not intended for use for general Ebola virus infection screening, such as airport screening or contact tracing. The ReEBOV™ Antigen Rapid Test is authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics). On March 10, 2015, FDA received a request from Corgenix Inc. for an amendment to the Emergency Use Authorization (EUA). In response to that request, and having concluded that revising the February 24, 2015, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), the February 24, 2015, letter authorizing the emergency use of the ReEBOV™ Antigen Rapid Test is being reissued in its entirety with the amendments incorporated.[2]

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus presents a material threat against the United States population sufficient to affect national security.[3] Pursuant to section 564(b)(1) of the Act

[1] This assay is intended for the qualitative detection of antigen from Zaire Ebola virus [detected in the West Africa outbreak in 2014), Sudan Ebola virus, and Bundibugyo Ebola virus; however, it does not distinguish between these different Ebola virus strains.

[2] The amendments to the February 24, 2015, letter allow, in addition to Corgenix Inc., distributors that are authorized by Corgenix Inc. to distribute the ReEBOV™ Antigen Rapid Test with certain conditions applicable to such authorized distributor(s). The Instructions for Use have also been updated to incorporate these amendments.

[3] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat pursuant to section 319F-2 of the PHS Act sufficient to affect national security or the health and security of United States citizens living abroad (section 564(b)(1)(D) of the Act).

(21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of the Department of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[4]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the ReEBOV™ Antigen Rapid Test (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection) (as described in the Scope of Authorization section of this letter (section II)) for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola viruses (detected in the West Africa outbreak in 2014) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Ebola Zaire virus (detected in the West Africa outbreak in 2014) can cause Ebola virus disease, a serious or life-threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the ReEBOV™ Antigen Rapid Test may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, and that the known and potential benefits of the ReEBOV™ Antigen Rapid Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the ReEBOV™ Antigen Rapid Test for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized ReEBOV™ Antigen Rapid Test for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors

[4] U.S. Department of Health and Human Services. *Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus*. 79 Fed. Reg. 47141 (August 12, 2014).

[5] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

(including geographic locations with high prevalence of Ebola infection). The authorized ReEBOV™ Antigen Rapid Test is intended for circumstances when use of a rapid Ebola virus test is determined to be more appropriate than use of an authorized Ebola virus nucleic acid test, which has been demonstrated to be more sensitive in detecting the Ebola Zaire virus. The authorized ReEBOV™ Antigen Rapid Test is not intended for use for general Ebola infection screening, such as airport screening or contact tracing. The ReEBOV™ Antigen Rapid Test is authorized for use in laboratories or facilities adequately equipped, trained, and capable of such testing (including treatment centers and public health clinics).

The Authorized ReEBOV™ Antigen Rapid Test

The ReEBOV™ Antigen Rapid Test is a chromatographic dipstick-format lateral flow immunoassay for the *in vitro* qualitative detection of VP40 protein from the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in fingerstick (capillary) whole blood, venous whole blood, plasma, and other authorized specimen types from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection). The test procedure consists of a dipstick-format lateral flow immunoassay that is initiated by applying the clinical specimen to the dipstick sample pad followed by insertion of the dipstick into a test tube containing sample buffer which initiates flow within the dipstick device. The test is then incubated for 15-25 minutes before being visually interpreted. The ReEBOV™ Antigen Rapid Test is a point-of-care test.

The ReEBOV™ Antigen Rapid Test consists of a self-contained, disposable dipstick-format lateral flow test that includes an internal process Control Line. Following application of the clinical specimen and insertion into the test tube containing sample buffer, the specimen flows through the reagent pads causing the Ebola Zaire virus antigen, VP40 protein, present in the specimen, to bind nanoparticles labeled with antigen specific antibodies. As the specimen and nanoparticles flow across the device membrane, immobilized Ebola Zaire virus antigen-specific antibody absorbs the nanoparticle immune-complexes at the Test Line. Antigen dependent deposition of the nanoparticle at the Test Line generates a chromogenic signal relative to the antigen titer. The test is incubated for 15-25 minutes to allow full development of the signal. The test result is determined by visual interpretation of the signal in the Test and Control Lines, with a positive sample resulting in development of a faint pink to dark red signal on the Test Line. Once a clinical specimen is collected and the test is initiated, it takes 15-25 minutes to produce results.

The ReEBOV™ Antigen Rapid Test includes the following internal process Control Line:

- The Process Control Line, located following the Test Line on the dipstick, is comprised of Ebola Zaire virus antigen and binds excess or unreacted nanoparticles resulting in a visual pink to red line. A visual signal on the Control Line indicates that the test was performed correctly and that the coated nanoparticles are reactive to the Ebola Zaire virus antigen.

The above described ReEBOV™ Antigen Rapid Test, when labeled consistently with the labeling authorized by FDA entitled "ReEBOV™ Antigen Rapid Test Instructions for Use"

(available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Corgenix Inc. in consultation with FDA, is authorized to be distributed to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described ReEBOV™ Antigen Rapid Test is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:

- Fact Sheet for Health Care Providers: Interpreting ReEBOV™ Antigen Rapid Test Results
- Fact Sheet for Patients: Understanding Results from the ReEBOV™ Antigen Rapid Test

As described in section IV below, Corgenix Inc. and its authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized ReEBOV™ Antigen Rapid Test that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized ReEBOV™ Antigen Rapid Test in the specified population, when used for presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized ReEBOV™ Antigen Rapid Test may be effective in the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available to FDA including the information supporting the conclusions described in section I above, and concludes that the authorized ReEBOV™ Antigen Rapid Test, when used to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized ReEBOV™ Antigen Rapid Test under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (section II) and the Conditions of Authorization (section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the ReEBOV™ Antigen Rapid Test described above is authorized to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors (including geographic locations with high prevalence of Ebola infection).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the ReEBOV™ Antigen Rapid Test during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820, with respect to the design, manufacture, packaging, labeling, storage, and distribution of the ReEBOV™ Antigen Rapid Test.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Corgenix Inc. and its Authorized Distributor(s)

A. Corgenix Inc. and its authorized distributor(s) will distribute the authorized ReEBOV™ Antigen Rapid Test with the authorized labeling, as may be revised only by Corgenix Inc. in consultation with FDA, to laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics).

B. Corgenix Inc. and its authorized distributor(s) will provide to laboratories and facilities (including treatment centers and public health clinics) adequately equipped, trained, and capable of testing for Ebola infection the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers and the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients.

C. Corgenix Inc. and its authorized distributor(s) will make available on their websites the ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers and the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients.

D. Corgenix Inc. and its authorized distributor(s) will inform laboratories, facilities adequately equipped, trained, and capable of testing for Ebola infection (including

treatment centers and public health clinics), and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Corgenix Inc. and its authorized distributor(s) will ensure that laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the authorized ReEBOV™ Antigen Rapid Test have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

F. Through a process of inventory control, Corgenix Inc. and its authorized distributor(s) will maintain records of device usage.

G. Corgenix Inc. and its authorized distributor(s) will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Corgenix Inc. and its authorized distributor(s) becomes aware.

H. Corgenix Inc. and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized ReEBOV™ Antigen Rapid Test that is consistent with, and does not exceed, the terms of this letter of authorization.

Corgenix Inc.

I. Corgenix Inc will notify FDA of any authorized distributor(s) of the ReEBOV™ Antigen Rapid Test, including the name, address, and phone number of any authorized distributor(s).

J. Corgenix Inc. will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

K. Corgenix Inc. only may request changes to the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Health Care Providers or the authorized ReEBOV™ Antigen Rapid Test Fact Sheet for Patients. Such requests will be made only by Corgenix Inc. in consultation with FDA.

L. Corgenix Inc. may request the addition of other specimen types for use with the authorized ReEBOV™ Antigen Rapid Test. Such requests will be made by Corgenix Inc. in consultation with, and require concurrence of, FDA.

M. Corgenix Inc. will track adverse events and report to FDA under 21 CFR Part 803.

Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection

N. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will include with reports of the results of the ReEBOV™ Antigen Rapid Test the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

O. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

P. Laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will collect information on the performance of the assay, and report to Corgenix Inc. and its authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.

Q. All laboratory personnel and personnel from facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) using the assay will be appropriately trained on the ReEBOV™ Antigen Rapid Test and use appropriate laboratory and personal protective equipment when handling this kit.

Corgenix Inc., its Authorized Distributors(s), and Laboratories and Facilities Adequately Equipped, Trained, and Capable of Testing for Ebola Infection

R. Corgenix Inc., its authorized distributor(s), and laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics) will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

S. All advertising and promotional descriptive printed matter relating to the use of the authorized ReEBOV™ Antigen Rapid Test shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

T. All advertising and promotional descriptive printed matter relating to the use of the authorized ReEBOV™ Antigen Rapid Test shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;

Page 8 – Mr. Simpson, Corgenix Inc.

- This test has been authorized by FDA under an Emergency Use Authorization for use by laboratories and facilities adequately equipped, trained, and capable of testing for Ebola infection (including treatment centers and public health clinics);
- This test has been authorized only for the detection of Ebola viruses (including Ebola Zaire virus detected in the West Africa outbreak in 2014); and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola Zaire virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized ReEBOV™ Antigen Rapid Test may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The emergency use of the authorized ReEBOV™ Antigen Rapid Test described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosures

The Authorization for the Cepheid Xpert® Ebola Assay issued on March 23, 2015, in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 23, 2015

James F. Kelly, Ph.D.
Executive Director, Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089

Dear Dr. Kelly:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of the Xpert® Ebola Assay for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) on the GeneXpert Instrument Systems in EDTA venous whole blood specimens from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors, by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests and by laboratories certified under CLIA to perform high complexity tests,[1] or in similarly qualified non-U.S. laboratories, by clinical laboratory personnel who have received specific training on the use of the Xpert® Ebola Assay on GeneXpert Instrument Systems, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus presents a material threat against the United States population sufficient to affect national security.[2] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of the Department of Health and Human Services (HHS) declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[3]

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Xpert® Ebola Assay (as described in the Scope of Authorization section of this letter (section II)) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk

[1] For ease of reference, this letter will refer to these two types of laboratories together as "CLIA Moderate and High Complexity Laboratories."
[2] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), the HHS Secretary's declaration that supports EUA issuance must be based on one of four determinations, including the identification by the DHS Secretary of a material threat pursuant to section 319F-2 of the PHS Act sufficient to affect national security or the health and security of United States citizens living abroad (section 564(b)(1)(D) of the Act).
[3] U.S. Department of Health and Human Services. *Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Ebola Virus*. 79 Fed. Reg. 47141 (August 12, 2014).

factors (as described in the Scope of Authorization section of this letter (section II)) for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the Xpert® Ebola Assay for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Ebola Zaire virus (detected in the West Africa outbreak in 2014) can cause Ebola virus disease, a serious or life-threatening disease or condition to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Xpert® Ebola Assay may be effective in diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, and that the known and potential benefits of the Xpert® Ebola Assay for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection, outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of the Xpert® Ebola Assay for diagnosing Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection.[4]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Xpert® Ebola Assay in CLIA Moderate and High Complexity Laboratories or in similarly qualified non-U.S. laboratories for the presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014) in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

The Authorized Xpert® Ebola Assay

The Xpert® Ebola Assay is an automated test intended for the *in vitro* qualitative detection of Ebola Zaire virus RNA from EDTA venous whole blood specimens. The assay is performed on the Cepheid GeneXpert Instrument Systems. GeneXpert Instrument Systems automate and integrate sample preparation, nucleic acid extraction, amplification, and detection of the target sequence in simple or complex samples using real-time reverse transcriptase PCR (rRT-PCR). The systems consist of an instrument, personal computer, and preloaded software for running tests and viewing the results. The test is run in single-use disposable GeneXpert cartridges that hold the sample extraction and rRT-PCR reagents and run the sample preparation and rRT-PCR processes. Because the cartridges are self-contained, cross-contamination between samples is minimized. End users collect the sample, transfer it to a sample transport tube containing a

[4] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

buffer that inactivates virus, and transfer the inactivated virus sample to the cartridge. All subsequent steps of sample extraction, amplification, and detection are fully automated.

Each Xpert® Ebola Assay includes a Sample Adequacy Control (SAC), Sample Processing Control (SPC), and Probe Check Control (PCC):

- Sample Adequacy Control (SAC): Ensures that the sample was correctly added to the cartridge. The SAC verifies that the correct volume of sample has been added in the sample chamber. The SAC passes if it meets the validated acceptance criteria.

- Sample Processing Control (SPC): Ensures the sample was correctly processed. The SPC is an Armored RNA® in the form of a dry bead that is included in each cartridge to verify adequate processing of the sample virus. The SPC verifies that lysis of Ebola has occurred if the organism is present and verifies that the specimen processing is adequate. Additionally this control detects specimen-associated inhibition of the RT-PCR reaction. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the validated acceptance criteria. The SPC is also referred to as the Cepheid Internal Control (CIC).

- Probe Check Control (PCC): Before the start of the PCR reaction, the GeneXpert Instrument System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, probe integrity, and dye stability. There are two probe check controls. The first PCC occurs after sample processing but before the start of the RT-PCR reaction and the second PCC occurs before the PCR reaction starts. The PCCs pass if they meet the validated acceptance criteria.

The above described Xpert® Ebola Assay, when labeled consistently with the labeling authorized by FDA entitled "Xpert® Ebola Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised by Cepheid in consultation with FDA, is authorized to be distributed to and used by CLIA Moderate and High Complexity Laboratories and similarly qualified non-U.S. laboratories, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Xpert® Ebola Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care professionals and patients:

- Fact Sheet for Health Care Providers: Interpreting Xpert® Ebola Assay Results

- Fact Sheet for Patients: Understanding Results from the Cepheid® Xpert® Ebola Assay

As described in section IV below, Cepheid and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized Xpert® Ebola Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Xpert® Ebola Assay in the specified population, when used for presumptive detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Xpert® Ebola Assay may be effective in the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available to FDA including the information supporting the conclusions described in section I above, and concludes that the authorized Xpert® Ebola Assay, when used to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in the specified population, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Xpert® Ebola Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (section II) and the Conditions of Authorization (section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Xpert® Ebola Assay described above is authorized to diagnose Ebola Zaire virus (detected in the West Africa outbreak in 2014) infection in individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for the Xpert® Ebola Assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Xpert® Ebola Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Cepheid and Any Authorized Distributor(s)

A. Cepheid and any authorized distributor(s) will distribute the authorized Xpert® Ebola Assay with the authorized labeling, as may be revised only by Cepheid in consultation with FDA, to CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories.

B. Cepheid and any authorized distributor(s) will provide to CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories the authorized Xpert® Ebola Assay Fact Sheet for Health Care Providers and the authorized Xpert® Ebola Assay Fact Sheet for Patients.

C. Cepheid and any authorized distributor(s) will make available on their websites the Xpert® Ebola Assay Fact Sheet for Health Care Providers and the authorized Xpert® Ebola Assay Fact Sheet for Patients.

D. Cepheid and any authorized distributor(s) will inform CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

E. Cepheid and any authorized distributor(s) will ensure that CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories using the authorized Xpert® Ebola Assay have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

F. Through a process of inventory control, Cepheid and any authorized distributor(s) will maintain records of device usage.

G. Cepheid and any authorized distributor(s) will collect information on the performance of the assay, and report to FDA any suspected occurrence of false positive or false negative results of which Cepheid and any authorized distributor(s) become aware.

H. Cepheid and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Xpert® Ebola Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

Cepheid

I. Cepheid will notify FDA of any authorized distributor(s) of the Xpert® Ebola Assay, including the name, address, and phone number of any authorized distributor(s).

J. Cepheid will provide any authorized distributor(s) with a copy of this EUA, and communicate to any authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

K. Cepheid only may request changes to the authorized Xpert® Ebola Assay Fact Sheet for Health Care Providers or the authorized Xpert® Ebola Assay Fact Sheet for Patients. Such requests will be made only by Cepheid in consultation with FDA.

L. Cepheid may request the addition of other specimen types for use with the authorized Xpert® Ebola Assay. Such requests will be made by Cepheid in consultation with, and require concurrence of, FDA.

M. Cepheid will track adverse events and report to FDA under 21 CFR part 803.

CLIA Moderate and High Complexity Laboratories or Similarly Qualified Non-U.S. Laboratories

N. CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories will include with reports of the results of the Xpert® Ebola Assay the authorized Fact Sheet for Health Care Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

O. CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories will have a process in place for reporting test results to health care professionals and relevant public health authorities, as appropriate.

P. CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories will collect information on the performance of the assay, and report to Cepheid and any authorized distributor(s) any suspected occurrence of false positive or false negative results of which they become aware.

Q. All laboratory personnel using the assay will be appropriately trained on the use of the Xpert® Ebola Assay on GeneXpert Instrument Systems and use appropriate laboratory and personal protective equipment when handling this kit.

Cepheid, Any Authorized Distributors, and CLIA Moderate and High Complexity Laboratories or Similarly Qualified Non-U.S. Laboratories

R. Cepheid, any authorized distributor(s), and CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

S. All advertising and promotional descriptive printed matter relating to the use of the authorized Xpert® Ebola Assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

Page 7 – Dr. James F. Kelly, Cepheid

T. All advertising and promotional descriptive printed matter relating to the use of the authorized Xpert® Ebola Assay shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by CLIA Moderate and High Complexity Laboratories or similarly qualified non-U.S. laboratories;
- This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014); and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of the authorized Xpert® Ebola Assay may represent or suggest that this test is safe or effective for the diagnosis of Ebola Zaire virus (detected in the West Africa outbreak in 2014).

The emergency use of the authorized Xpert® Ebola Assay described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of Ebola virus is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

Enclosure

Dated: May 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–13699 Filed 6–4–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by July 6, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title. Also include the FDA docket number found in brackets in the heading of this document.