an application. The submission deadline for the application has been extended to August 1, 2013.

DATES: *Letter of Intent Submission Deadline:* Interested organizations must submit a non-binding letter of intent on or before July 19, 2013, by an online form at: *https://cmsgov.secure.force.com/cec.*

Application Submission Deadline: Interested organizations must submit an application on or before August 1, 2013, as described on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/comprehensive-ESRD-care/apply.html.* Interested organizations should also continue to check the Web site for updates on this initiative.

FOR FURTHER INFORMATION CONTACT: Melissa Cohen, (410) 786–1829 or *ESRD-CMMI@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Medicare and Medicaid Innovation (Innovation Center) is interested in identifying models designed to improve care for beneficiaries with end-stage renal disease (ESRD). To promote seamless and integrated care for beneficiaries with ESRD, we are developing a comprehensive care delivery model to emphasize coordination of a full-range of clinical and non-clinical services across providers, suppliers, and settings. Through the Comprehensive ESRD Care Model, we seek to identify ways to improve the coordination and quality of care for this population, while lowering total per-capita expenditures under the Medicare program. We anticipate that the Comprehensive ESRD Care Model would result in improved health outcomes for beneficiaries with ESRD regarding the functional status, quality of life, and overall well-being, as well as increased beneficiary and caregiver engagement, and lower costs to Medicare through improved care coordination.

On February 6, 2013, we published a notice in the **Federal Register** announcing a request for applications from organizations to participate in the testing of the Comprehensive ESRD Care Model, for a period beginning in 2013 and ending in 2016, with a possible extension into subsequent years.

In that notice, we stated that organizations interested in applying to participate in the testing of the Comprehensive ESRD Care Model must submit a non-binding letter of intent by March 15, 2013, and an application by May 1, 2013.

II. Provisions of the Notice

Since the publication of the February 6, 2013 notice, several stakeholders have requested additional time to prepare their applications and form partnerships. Therefore, the Innovation Center is extending the following deadlines relating to the Comprehensive ESRD Care initiative: (1) The letter of intent submission period has been reopened. The deadline for submission of the letter of intent has been extended to July 19, 2013; and (2) the deadline for submission of the application has been extended to August 1, 2013.

In the **DATES** section of this notice, we are including the new submissions deadlines. For additional information on the Comprehensive ESRD Care Model and how to apply, we refer readers to click on the Request for Applications located on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/comprehensive-ESRD-care.*

(No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare-Supplementary Medical Insurance Program)

Dated: July 9, 2013.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–17131 Filed 7–16–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0754]

Authorization of Emergency Use of an In Vitro Diagnostic for Detection of Middle East Respiratory Syndrome Coronavirus; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), formerly known as Novel Coronavirus 2012 or NCV–2012. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic (the FD&C) Act, as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the determination by the Secretary of Health and Human Services (HHS) that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves MERS-CoV. On the basis of such determination, the Secretary also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of MERS-CoV subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

DATES: The Authorization is effective as of June 5, 2013.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4121, 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 Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Luciana Borio, Assistant Commissioner for Counterterrorism Policy, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4118, Silver Spring, MD 20993–0002, telephone 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 EUAauthority, 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; [1] or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F–2 of the Public Health Service (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 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 CDC (to the extent feasible and appropriate given the applicable circumstances), FDA [2] 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 the Secretary of HHS may by regulation prescribe are satisfied.

No other criteria of 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 Request for an In Vitro Diagnostic for Detection of MERS-CoV

On May 29, 2013, under section 564(b)(1)(C) of the FD&C Act (21 U.S.C. 360bbb–3(b)(1)(C)), the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves MERS-CoV. Also on May 29, 2013, 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 MERS-CoV, subject to the terms of any authorization issued under section 564 of the FD&C Act. On May 31, 2013, CDC requested, and on June 5, 2013, FDA issued, an EUA for the CDC Novel Coronavirus 2012 Real-time RT–PCR Assay subject to the terms of this authorization.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov.*

IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of MERS-CoV subject to the terms of the Authorization. The Authorization 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 4160–01–P

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, the Secretary of HHS may make a determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency under section 319 of the PHS Act, 42 U.S.C. 247d, to support a determination made under section 564 of the FD&C Act.

[2] 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

June 5, 2013

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
Atlanta, GA 30333

Dear Dr. Frieden:

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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV), formerly known as Novel Coronavirus 2012 or NCV-2012, in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), by qualified laboratories.

On May 29, 2013, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States 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 an agent or agents—in this case, Middle East Respiratory Syndrome Coronavirus (MERS-CoV).[1] 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 HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for the detection of MERS-CoV, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[2]

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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (as described in the scope section of this letter (Section II)) for the presumptive detection of MERS-CoV in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

[1] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[2] Memorandum, Determination of a Significant Potential for a Public Health Emergency and Declaration that Circumstances Exist Justifying an Authorization Pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (May 29, 2013).

Page 2 – Dr. Frieden, Centers for Disease Control and Prevention

I have concluded that the emergency use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. MERS-CoV can cause a serious or life threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in diagnosing MERS-CoV, and that the known and potential benefits of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used for diagnosing MERS-CoV 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for diagnosing MERS-CoV.[3]

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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay for the presumptive detection of MERS-CoV in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors.

The Authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay:

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay is a real-time reverse transcriptase PCR (rRT-PCR) for the *in vitro* qualitative detection of MERS-CoV viral RNA from respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputa, lower respiratory aspirates/washes), sera, and stool from patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors. The testing procedure consists of nucleic acid extraction followed by rRT-PCR on the FDA cleared Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument.

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay includes the following primer and probe sets:

NCV.N2:	Targets the MERS-CoV nucleocapsid protein gene
NCV.N3:	Targets the MERS-CoV nucleocapsid protein gene
NCV.upE[4]:	Targets the MERS-CoV region upstream of envelope protein gene
RP[5]:	Targets the human Ribonuclease P gene. This primer and probe set is included as a control for specimen quality, to confirm that human

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

[4] This is a WHO-recommended MERS-CoV primer and probe set. See Corman VM, et al. Detection of a novel human coronavirus by real-time reverse-transcription polymerase chain reaction. *Euro Surveill*. 2012;17(39). Available online at: http://www.eurosurveillance.org/images/dynamic/EE/V17N39/art20285.pdf.

[5] This primer and probe set is not provided in the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Kit, but it is required for test performance. Laboratories will utilize the Laboratory Response Network (LRN) RNase P Real-time PCR Primer and Probe Set.

nucleic acid was successfully extracted from the clinical specimen.

The CDC Novel Coronavirus 2012 Real-time RT-PCR Assay also includes the following control materials:

- **Positive Control**: NCV-2012 rRT-PCR Assay Positive Control (VTC)
- **Negative Controls**: Sterile, nuclease-free water, used as No Template Control (NTC)
  1. **PCR No Template Control (NTC_1)**
  2. **Extraction control (NTC_2)**

The above described CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when labeled consistently with the labeling authorized by FDA, titled "CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Instructions for Use" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), which may be revised with written permission of FDA, is authorized to be distributed to and used by qualified laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described CDC Novel Coronavirus 2012 Real-time RT-PCR 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 Professionals: Interpreting CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Test Results**

- **Fact Sheet for Patients: Understanding Results from the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay**

As described in section IV below, CDC is also authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay in the specified population, when used for presumptive detection of MERS-CoV, 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may be effective in the diagnosis of MERS-CoV infection pursuant to section 564(c)(2)(A) of the Act. The FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and concludes that the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay, when used to diagnose MERS-CoV 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section

564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay described above is authorized to diagnose MERS-CoV infection in patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors.

This EUA will cease to be effective when the declaration of emergency 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay during the duration of this emergency use authorization:

- 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 CDC Novel Coronavirus 2012 Real-time RT-PCR Assay.

- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 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) 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:

CDC

A. CDC will distribute the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay with the authorized labeling, as may be revised with written permission of FDA, only to qualified laboratories.
B. CDC will provide to the qualified laboratories the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients.
C. CDC will make available on its website the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals and the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients.
D. CDC will inform state and/or local public health authority(ies) of this EUA, including the terms and conditions herein.
E. CDC will ensure that qualified laboratories using the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.
F. CDC will track adverse events and report to FDA as required under 21 CFR Part 803.

G. Through a process of inventory control, CDC will maintain records of device usage.
H. CDC 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 CDC becomes aware.
I. CDC is authorized to make available additional information relating to the emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay that is consistent with, and does not exceed, the terms of this letter of authorization.
J. Only CDC may request changes to the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Health Care Professionals or the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay Fact Sheet for Patients. Such requests will be made by contacting FDA concerning FDA review and approval.

Qualified Laboratories

K. Qualified laboratories will make available the authorized Fact Sheet for Health Care Professionals and the authorized Fact Sheet for Patients.
L. Qualified laboratories will perform the assay on an Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with the appropriate software.
M. Qualified laboratories will have a process in place for reporting test results to health care professionals and federal, state, and/or local public health authorities, as appropriate.
N. Qualified laboratories will collect information on the performance of the assay, and report to CDC any suspected occurrence of false positive or false negative results of which qualified laboratories become aware.

CDC and Qualified Laboratories

O. CDC and qualified 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

P. All advertising and promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay will be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and other requirements set forth in the Act and FDA regulations.

Q. All advertising and promotional descriptive printed matter relating to the use of the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay will clearly and conspicuously state that:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an Emergency Use Authorization for use by qualified laboratories;
- This test has been authorized only for the detection of MERS-CoV and not for any other viruses or pathogens; and

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- 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 MERS-CoV under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1).

R. No advertising or promotional descriptive printed matter relating to the use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay may represent or suggest that this test is safe or effective for the diagnosis of MERS-CoV.

The emergency use of the authorized CDC Novel Coronavirus 2012 Real-time RT-PCR Assay as described in this letter of authorization must comply with the conditions above 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 MERS-CoV is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

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

Enclosures

Dated: July 11, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–17103 Filed 7–16–13; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0592]

Yuri Izurieta; Conviction Reversal; Final Order Withdrawing Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), withdrawing its January 25, 2012, order debarring Yuri Izurieta from importing food or offering food for importation into the United States. FDA is issuing this order because the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Yuri Izurieta.

DATES: *Effective Date:* July 17, 2013.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** on January 25, 2012 (77 FR 3776), FDA debarred Yuri Izurieta for a period of 20 years from importing articles of food or offering such articles for importation into the United States. FDA issued the debarment order under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)), which permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food. The debarment was based on FDA's finding that Mr. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Izurieta was convicted on May 11, 2011, in the U.S. District Court for the Southern District of Florida and sentenced on July 29, 2011, for conspiracy to smuggle goods into the United States and smuggling goods into the United States. The basis for Mr. Izurieta's conviction was his alleged role in distributing shipments of dairy products that were adulterated and not authorized for entry into the United States. On August 3, 2011, Mr. Izurieta appealed his conviction and sentence.

On February 22, 2013, the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Mr. Izurieta. A copy of the court's order is available in Docket No. FDA–2011–N–0592. By this order, the court vacated Mr. Izurieta's conviction. The order was issued as a mandate on April 23, 2013. Section 306(d)(3)(B)(i) of the FD&C Act (U.S.C. 335a(d)(3)(B)(i)) states that ''If the conviction which served as the basis for the debarment of an individual under subsection . . . (b)(3) is reversed, the Secretary shall withdraw the order of debarment.'':

Accordingly, the Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(d)(3)(B)(i) of the FD&C Act and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), issues this order withdrawing the order of debarment of Yuri Izurieta, thereby allowing him to import food or offer such articles for importation into the United States. This order is effective July 17, 2013.

Dated: July 12, 2013.

Melinda K. Plaisier,

Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs.

[FR Doc. 2013–17122 Filed 7–16–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0589]

Anneri Izurieta; Conviction Reversal; Final Order Withdrawing Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The U.S. Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), withdrawing its January 13, 2012, order debarring Anneri Izurieta from importing food or offering food for importation into the United States. FDA is issuing this order because the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Anneri Izurieta.

DATES: *Effective Date:* July 17, 2013.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** on January 13, 2012 (77 FR 2070), FDA debarred Anneri Izurieta for a period of 30 years from importing articles of food or offering such articles for importation into the United States. FDA issued the debarment order under section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)), which permits FDA to debar an individual from importing an article of food or offering such an article for importation into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act (21 U.S.C. 335a(b)(3)(A)), that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food. The debarment was based on FDA's finding that Ms. Izurieta was convicted of six felony counts under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Izurieta, the president and director of Naver Trading, was convicted on May 11, 2011, and sentenced on July 29, 2011, for conspiracy to smuggle goods into the United States and smuggling goods into the United States. The basis for Ms. Izurieta's conviction was her alleged role in distributing shipments of dairy products that were adulterated and not authorized for entry into the United States. On August 3, 2011, Ms. Izurieta appealed her conviction and sentence.

On February 22, 2013, the U.S. Court of Appeals for the Eleventh Circuit issued an order vacating the conviction and sentence of Ms. Izurieta. A copy of the court's order is available in Docket No. FDA–2011–N–0589. By this order, the court vacated Ms. Izurieta's conviction. The order was issued as a mandate on April 23, 2013. Section 306(d)(3)(B)(i) of the FD&C Act (U.S.C. 335a(d)(3)(B)(i) states that ''If the conviction which served as the basis for the debarment of an individual under subsection . . . (b)(3) is reversed, the Secretary shall withdraw the order of debarment.''

Accordingly, the Acting Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(d)(3)(B)(i) of the FD&C Act and under authority delegated to the