procedures, applications for maximum residue limits, clinical trial applications, drug/active substance master files, or requests for regulatory or scientific advice.

III. Significance of Guidance

This guidance, developed under the VICH process, has been revised to conform with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather ''guideline''. In addition, guidance documents must not include mandatory language such as ''shall'', ''must'', ''require'', or ''requirements'', unless FDA is using these words to describe a statutory or regulatory requirement. The guidance represents the current thinking of FDA on electronic exchange of documents: Electronic file format. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of applicable statutes and regulations.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

V. Comments

Interested persons may submit either electronic comments regarding this document 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.*

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov.*

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21582 Filed 8–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3042]

Authorization of Emergency Use of an In Vitro Diagnostic Device 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). FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by altona Diagnostics GmbH. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the May 29, 2013, determination by the Department of Health and Human Services (HHS) Secretary 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 of HHS also declared on May 29, 2013, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic devices 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 July 17, 2015.

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. 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 Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

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 (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.

[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.

II. EUA Request for an In Vitro Diagnostic Device 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 diagnostic devices for detection of MERS-CoV, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on June 5, 2013 (78 FR 33842). On June 26, 2015, altona Diagnostics GmbH submitted a complete request for, and on July 17, 2015, FDA issued, an EUA for the altona Diagnostics GmbH RealStar® MERS-CoV RT–PCR Kit U.S., subject to the terms of the 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 4164–01–P

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

July 17, 2015

Dr. Sven Cramer
Head of Regulatory Affairs
altona Diagnostics GmbH
Mörkenstraße 12
22767 Hamburg
Germany

Dear Dr. Cramer:

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 RealStar® MERS-CoV RT-PCR Kit U.S. for the *in vitro* qualitative detection of RNA from the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), formerly known as Novel Coronavirus 2012 or NCV-2012, in lower respiratory specimens (tracheal aspirate/tracheal secretions) from individuals with signs and symptoms of infection with MERS-CoV in conjunction with epidemiological risk factors for the presumptive detection of MERS-CoV, by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests,[1] and similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

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 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 MERS-CoV.[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 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 section 564(a) of the Act (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 RealStar® MERS-CoV RT-PCR Kit U.S. (as described in the Scope of Authorization section of this letter (Section II)) for the presumptive detection of MERS-CoV from individuals with signs and symptoms of infection with MERS-CoV in conjunction with epidemiological risk factors.

[1] For ease of reference, this letter will refer to this type of laboratory as "CLIA High Complexity Laboratories."
[2] 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.
[3] HHS. *Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV).* 78 Fed. Reg. 33842 (June 5, 2013).

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the RealStar® MERS-CoV RT-PCR Kit U.S. for the presumptive detection of MERS-CoV 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. MERS-CoV can cause a serious or life threatening disease or condition, including severe respiratory illness, to humans infected with this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the RealStar® MERS-CoV RT-PCR Kit U.S. when used with the specified instruments may be effective in diagnosing MERS-CoV infection, and that the known and potential benefits of the RealStar® MERS-CoV RT-PCR Kit U.S., 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 RealStar® MERS-CoV RT-PCR Kit U.S. for diagnosing MERS-CoV.[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 RealStar® MERS-CoV RT-PCR Kit U.S. by CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories for the *in vitro* qualitative detection of RNA from MERS-CoV in individuals with signs and symptoms of infection with MERS-CoV in conjunction with epidemiological risk factors, for the presumptive detection of MERS-CoV.

The Authorized RealStar® MERS-CoV RT-PCR Kit U.S.

The RealStar® MERS-CoV RT-PCR Kit U.S. is a real-time reverse transcriptase polymerase chain reaction (rRT-PCR) for the *in vitro* qualitative detection of RNA from MERS-CoV in lower respiratory specimens (tracheal aspirate/tracheal secretions) from individuals with signs and symptoms of infection with MERS-CoV in conjunction with epidemiological risk factors. The test procedure consists of nucleic acid extraction using the QIAamp® Viral RNA Mini Kit, or other authorized extraction methods followed by rRT-PCR on Applied Biosystems PCR instrument systems (i.e., ABI Prism® 7500 SDS, ABI Prism® 7500 Fast SDS), Roche LightCycler® 480 Instrument II, BIO-RAD PCR instrument system (i.e., CFX96™ system/Dx real-time system, CFX96 Touch™ Deep Well Real-Time PCR Detection System), Corbett Research Rotor-Gene® 6000, QUIAGEN Rotor-Gene® Q5/6 plex/MDx Platform, and Siemens VERSANT® kPCR Molecular System AD, or other authorized instruments.

The RealStar® MERS-CoV RT-PCR Kit U.S. consists of two independent assays, one targeting a region upstream of the E gene (*upE*) and the other targeting open reading frame 1a (*orf1a*) of the MERS-CoV genome. Both assays include a heterologous amplification system (Internal Control) to identify possible RT-PCR inhibition and to confirm the integrity of the reagents of the kit.

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

The test is based on rRT-PCR technology, utilizing reverse transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA), polymerase chain reaction (PCR) for the amplification of specific target sequences, and target specific probes for the detection of the amplified DNA. The probes are labeled with fluorescent reporter and quencher dyes. In both assays, probes specific for MERS-CoV RNA are labeled with the fluorophore FAM (amine-reactive succinimidyl esters of carboxyfluorescein).

The RealStar® MERS-CoV RT-PCR Kit U.S. uses the following primer and probe sets:

a) Detection of MERS-CoV *orf1a*:
- Forward primer: P1358
- Reverse primer: P1359
- Probe: S653

b) Detection of MERS-CoV *upE*:
- Forward primer: P1356
- Reverse primer: P1357
- Probe: S652

c) Detection of the Internal Control:
- Forward primer: P30
- Reverse primer: P31
- Probe: S116

Control material to be used with the RealStar® MERS-CoV RT-PCR Kit U.S. test includes:

a) Internal Control

The Internal Control contains a defined copy number of an "artificial" RNA molecule with no homologies to any other known sequences. It has to be added to the nucleic acid extraction procedure and is reverse transcribed, amplified, and detected in parallel to the MERS-CoV specific RNA. The function of the Internal Control is to ensure the integrity of MERS-CoV specific rRT-PCR results by indicating potential RT-PCR inhibition.

b) PCR grade water

The PCR grade water is to be used as negative control for the RT-PCR reaction. Its function is to indicate contamination of RT-PCR reagents.

c) Positive Control

The Positive Control consists of dilutions of a 1:1 mixture of two *in vitro* transcripts (IVT). One IVT with a length of 590 nt contains a sequence (399 nt) of open reading frame 1a of MERS-CoV, whereas the other IVT with a length of 590 nt contains a sequence (399 nt) upstream of the E gene of the MERS-CoV genome. The *orf1a* specific IVT as well as the *upE* specific IVT contain the target region for the *orf1a* and the *upE* specific detection system, respectively (399 nt in length for *orf1a* and 399 nt in length for *upE*) which is used

to detect MERS-CoV specific RNA with the RealStar® MERS-CoV RT-PCR Kit U.S. The Positive Control is used for the RT-PCR to verify the functionality of the MERS-CoV RNA specific RT-PCR detection system, which is included in the RealStar® MERS-CoV RT-PCR Kit U.S.

The above described RealStar® MERS-CoV RT-PCR Kit U.S., when labeled consistently with the labeling authorized by FDA, entitled "RealStar® MERS-CoV RT-PCR Kit U.S. Instructions for Use" (available at http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm), which may be revised only with written permission of FDA, is authorized to be distributed to and used by CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described RealStar® MERS-CoV RT-PCR Kit U.S. is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care providers and patients:

- Fact Sheet for Health Care Providers: Interpreting RealStar® MERS-CoV RT-PCR Kit U.S. Test Results
- Fact Sheet for Patients: Understanding Results from the RealStar® MERS-CoV RT-PCR Kit U.S.

As described in section IV below, altona Diagnostics GmbH and any authorized distributor(s) are also authorized to make available additional information relating to the emergency use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. 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 RealStar® MERS-CoV RT-PCR Kit U.S. in the specified population, when used for the *in vitro* qualitative detection of RNA from MERS-CoV in conjunction with epidemiological risk factors, 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 RealStar MERS-CoV RT-PCR Kit U.S. may be effective in the diagnosis of MERS-CoV infection pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available including the information supporting the conclusions described in Section I above, and has concluded that the authorized RealStar® MERS-CoV RT-PCR Kit U.S., when used to diagnose MERS-CoV infection in the specified population in conjunction with epidemiological risk factors, meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. 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 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 RealStar® MERS-CoV RT-PCR Kit U.S. described above is authorized to diagnose MERS-CoV infection in individuals with signs and symptoms of infection with MERS-CoV 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 RealStar® MERS-CoV RT-PCR Kit U.S. 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 RealStar® MERS-CoV RT-PCR Kit U.S.

- 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), (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:

altona Diagnostics GmbH and Any Authorized Distributor(s)

A. altona Diagnostics GmbH and any authorized distributor(s) will distribute the authorized RealStar® MERS-CoV RT-PCR Kit U.S. with the authorized labeling, as may be revised with written permission of FDA, only to CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories.

B. altona Diagnostics GmbH and any authorized distributor(s) will provide to CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Health Care Providers and the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Patients.

C. altona Diagnostics GmbH and any authorized distributor(s) will make available on their websites the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Health Care Providers and the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Patients.

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

E. altona Diagnostics GmbH and any authorized distributor(s) will ensure that CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories using the authorized RealStar® MERS-CoV RT-PCR Kit U.S. have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.

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

G. altona Diagnostics GmbH 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 altona Diagnostics GmbH and any authorized distributor(s) become aware.

H. altona Diagnostics GmbH and any authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. that is consistent with, and does not exceed, the terms of this letter of authorization.

altona Diagnostics GmbH

I. altona Diagnostics GmbH will notify FDA of any authorized distributor(s) of the RealStar® MERS-CoV RT-PCR Kit U.S., including the name, address, and phone number of any authorized distributor(s).

J. altona Diagnostics GmbH 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. altona Diagnostics GmbH only may request changes to the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Health Care Providers or the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Fact Sheet for Patients. Such requests will be made only by altona Diagnostics GmbH in consultation with FDA.

L. altona Diagnostics GmbH may request the addition of other specimen types for use with the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

M. altona Diagnostics GmbH may request the addition of other extraction methods for use with the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

N. altona Diagnostics GmbH may request the addition of other real-time PCR instruments for use with the authorized RealStar® MERS-CoV RT-PCR Kit U.S. Such requests will be made by altona Diagnostics GmbH in consultation with, and require concurrence of, FDA.

O. altona Diagnostics GmbH will track adverse events and report to FDA under 21 CFR part 803.

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

P. CLIA High Complexity Laboratories and similarly qualified non-U.S. laboratories will include with reports of the results of the RealStar® MERS-CoV RT-PCR Kit U.S 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.

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

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

S. All laboratory personnel using the assay will be appropriately trained on the use of the RealStar® MERS-CoV RT-PCR Kit U.S. on the specified instrument systems or other authorized instruments and use appropriate laboratory and personal protective equipment when handling this test.

altona Diagnostics GmbH, Any Authorized Distributor(s), CLIA High Complexity Laboratories, and Similarly Qualified Non-U.S. Laboratories

T. altona Diagnostics GmbH, any authorized distributor(s), CLIA High Complexity Laboratories, and 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

U. All advertising and promotional descriptive printed matter relating to the use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. will 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.

V. All advertising and promotional descriptive printed matter relating to the use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. will 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 High Complexity Laboratories and similarly qualified non-U.S. laboratories;

Page 8 – Dr. Cramer, altona Diagnostics GmbH

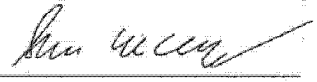
- This test has been authorized only for the detection of MERS-CoV; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostics for detection of MERS-CoV under section 564(b)(1) of the Act, 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 RealStar® MERS-CoV RT-PCR Kit U.S. may represent or suggest that this test is safe or effective for the diagnosis of MERS-CoV.

The emergency use of the authorized RealStar® MERS-CoV RT-PCR Kit U.S. as 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 MERS-CoV is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.



Stephen M. Ostroff, M.D.
Acting Commissioner of Food and Drugs

Enclosures

Dated: August 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–21585 Filed 8–31–15; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1492]

Two-Phased Chemistry, Manufacturing, and Controls Technical Sections; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI) #227 entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections.'' The guidance provides recommendations to sponsors submitting chemistry, manufacturing, and controls (CMC) data submissions to the Center of Veterinary Medicine (CVM) to support approval of a new animal drug or abbreviated new animal drug.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather Longstaff, Center for Veterinary Medicine (HFV–145), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0651, *heather.longstaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 20, 2014 (79 FR 62635) FDA published the notice of availability for a draft guidance for industry #227 entitled ''Two-Phased Chemistry, Manufacturing, and Controls (CMC) Technical Sections'' giving interested persons until December 19, 2014, to comment on the draft guidance. FDA received one comment on the draft guidance and that comment was considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated October 2014.

GFI #227 provides recommendations to sponsors submitting CMC data submissions to CVM to support approval of a new animal drug or abbreviated new animal drug. The two-phased process allows for two separate CMC submissions, each with its own review clock, and each including complete appropriate CMC information that is available for review at the time of submission. The guidance specifies the technical details of how the process works, the review clocks, the information that is appropriate for each technical section submission, and the possible review outcomes. The guidance also includes CVM's recommendations for meetings between the Division of Manufacturing Technologies and the sponsor during this process to ensure concurrence with the approach used for the CMC technical section.