U.S. FOOD & DRUG ADMINISTRATION

April 12, 2021

Rita Hoady, MS RAC CCRA
Senior Manager, Regulatory Affairs
Roche Molecular Systems, Inc.
4300 Hacienda Drive
Pleasanton, CA 94588

Device:	cobas SARS-CoV-2
Company:	Roche Molecular Systems, Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider and those without symptoms or other reasons to suspect COVID-19. Qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests, except testing of pooled samples is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Mrs. Hoady:

On March 12, 2020, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the cobas SARS-CoV-2, for use on the cobas 6800/8800 Systems for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to U.S. laboratories certified under the CLIA, 42 U.S.C. §263a, to perform moderate complexity tests and in U.S. laboratories certified under CLIA to perform high complexity tests, by clinical laboratory personnel who have received specific training on the use of the cobas 6800/8800 Systems. Based on your request, FDA has also granted updates to the authorized labeling on March 31, 2020[2] and May 13, 2020.[3] Based on your request, the March 12, 2020, letter was revised and reissued by FDA on October 15, 2020, to, among other requests, add pooling of patient specimens.[4] Subsequent minor updates were made at your request.[5]

On March 30, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the October 15, 2020, EUA is appropriate to

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Roche Molecular Systems, Inc.

[2] On March 31, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) include in the intended use the testing of "clinician-instructed self-collected (collected on Site) and clinician-collected nasal swab specimens," (2) addition of the cobas PCR Media provided in both the cobas PCR Media Uni Swab Sample Kit and the cobas PCR Media Dual Swab Sample Kit, and 0.9% Physiological Saline, as acceptable collection and transport media, (3) expand the claimed specimen types to include nasal, nasopharyngeal and oropharyngeal specimens collected according to standard collection technique using flocked or polyester-tipped swabs and immediately placed in 3 mL of Copan Universal Transport Medium (UTM-RT) or BD Universal Viral Transport (UVT), (4) expand the claimed specimen types to include nasal swab specimens collected using the cobas PCR Media Uni Swab Sample Kit (P/N 07958030190) or the cobas PCR Media Dual Swab Sample Kit (P/N 07958021190), (5) expand the claimed specimen types to include nasal swab specimens collected according to standard collection technique using flocked or polyester-tipped swabs immediately placed in 3 mL of 0.9% physiological saline, (6) add the specific instructions for collecting nasal swab specimens using either the cobas PCR Media Dual Swab Kit or the cobas PCR Media Uni Swab Kit, (7) make minor correcting/clarifying revisions. The Healthcare Provider fact sheet was also updated accordingly.

[3] On May 13, 2020, your request was granted to update the the Assay Specific Analysis Package (ASAP) software associated with the cobas 6800/8800 Systems performing the cobas SARS-CoV-2 test to; (1) allow use of the cobas PCR Media tube as the primary tube for processing without the need to remove the swab, (2) adjust liquid handling parameters to reduce dispense clot rates, and (3) adjust the PCR fluorescence curve analysis algorithm. In addition your request was granted to update the IFU of your product to: (1) add instructions for the cobas PCR Media primary tube processing, (2) add limit of detection study in copies/mL using the SeraCare AccuPlex material, (3) revise the Results Interpretation table by removing the need for retesting of presumptive positives based on real world data, (4) updated the Nasal swab collection pictogram, (5) corrections to confidence intervals in Table 15, and (6) other minor edits made for clarification and/or requested by FDA. Updates to the Healthcare Provider and Patient Fact Sheets were made to reflect more recent authorizations.

[4] The revisions to the March 12, 2020, letter and authorized labeling included: (1) revisions to the intended use and authorized labeling documents to include testing of pooled samples containing up to and including six individual samples from clinician-instructed self-collected nasal swab specimens (collected on site), or clinician-collected nasal, nasopharyngeal, and oropharyngeal swab specimens, (2) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations, and (3) revisions to the Conditions of Authorization as a result of the new intended use and for consistency with recent authorizations.

[5] A minor update to the IFU was granted via email on November 18, 2020, and a system software update that did not result in changes to the intended use, algorithm, and current labeling of your product was granted via email on January 11, 2021.

protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the October 15, 2020, letter in its entirety with the revisions incorporated.[6] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[7] is now authorized for use consistent with the indication described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is 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 the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[8]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product (as described in the scope Section of this letter (Section II)), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the cobas SARS-CoV-2 test in individuals who meet COVID-19 clinical and/or epidemiological criteria for testing meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

[6] The revisions to the October 15, 2020, letter and authorized labeling include: (1) revisions to the intended use and authorized labeling documents to include testing of specimens collection from any individuals, including those without symptoms or other reasons to suspect COVID-19, (2) revisions to the intended use and authorized labeling documents to update clinician to healthcare provider and to clarify nasal swab as meaning anterior nasal (nasal) swab speciments, (3) updates to the IFU and Fact Sheet for Healthcare providers to include limitations around performance of your product with newly emerging strains of SARS-CoV-2, (4) updates to the reactivity/inclusivity data, (5) updates to the clinical performance section with specimens collected from individuals suspected of COVID-19, (6) updates to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language consistent with recent authorizations, and (7) updates to the Conditions of Authorization to require a post-authorization clinical study to support the testing of individuals without symptoms or other reasons to suspect COVID-19 indication and to use language consistent with recent authorizations.

[7] For ease of reference, this letter will use the term "your product" to refer to the cobas SARS-CoV-2 used for the indication identified above.

[8] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.* § *360bbb-3*. 85 FR 7316 (February 7, 2020).

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the cobas SARS-CoV-2 may be effective in diagnosing COVID-19, and that the known and potential benefits of the cobas SARS-CoV-2 test, when used for diagnosing COVID-19, 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 cobas SARS-CoV-2 test for diagnosing COVID-19.[9]

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 indication above.

Authorized Product Details

Your product is a qualitative test, for use on the cobas 6800 System and cobas 8800 System for the detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider and those without symptoms or other reasons to suspect COVID-19.

Your product is also for the qualitative detection of nucleic acids from the SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens. Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive or presumptive positive result must be tested individually prior to reporting a result. Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories certified under CLIA that meet requirements to perform high or moderate complexity tests, except testing of pooled samples is limited to laboratories certified under CLIA that meet requirements to perform high complexity tests.

Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, recent exposures and epidemiological information.

Your product is based on fully automated sample preparation (nucleic acid extraction and purification) followed by reverse transcription, PCR amplification and detection on the cobas

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

6800/8800 system, or other authorized instruments. Automated data management is performed by the cobas 6800/8800 software, or otherwise authorized software, which assigns test results for all tests. Results can be reviewed directly on the system screen, and printed as a report.

Your product requires an RNA Internal Control, or other authorized internal control material (as may be requested under Condition K below), consisting of non-Sarbecovirus related armored RNA construct, that is added to each specimen and used as an extraction control that is extracted and tested concurrently with each specimen. The internal control is detected by an internal control specific primer and probe set and is used to monitor the entire sample preparation and PCR amplification process.

Nucleic acid from patient samples and added internal control RNA (RNA IC) molecules are simultaneously extracted and purified. Selective amplification of SARS-CoV-2 target nucleic acid from the sample is achieved by the use of target-specific forward and reverse primers for two SARS-CoV-2 targets, one from the SARS-CoV-2 specific ORF1 region and one from a conserved region of the envelope E-gene common to all SARS-like Coronaviruses (called Sarbecoviruses). The two targets are detected by sequence specific probes labeled with different fluorophores. The pan-Sarbecovirus detection sets will also detect the SARS-CoV-2 virus.

The cobas SARS-CoV-2 test includes the following materials or other authorized materials (as may be requested under Condition K below):

- cobas SARS-CoV-2 test cassettes containing all necessary reagents for the SARS-CoV-2 specific RT-PCR reaction including the RNA Internal Control RNA and the primers and probes for amplification and detection of the internal control and the SARS-CoV-2 sequences
- cobas SARS-CoV-2 Control Kit containing the SARS-CoV-2 Positive Control

In addition, your product requires the following external control materials, or other authorized control materials (as may be requested under Condition K below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- SARS-CoV-2 Positive Control: non-infectious plasmid DNA that include the following sequences: SARS-COV-2 sequence, pan-Sarbecovirus 1 sequence, and pan-Sarbecovirus sequence. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- cobas Buffer Negative Control: Tris buffer used to monitor for reagent and system contamination that is run with each batch of specimens.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test and are described in the Instructions for Use, including but not limited to the following:

- cobas Buffer Negative Control Kit
- cobas omni reagents and materials

The labeling entitled labeling entitled "cobas SARS-CoV-2 Instructions for Use", (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), the Product Information Card (PIC card), and the following fact sheets pertaining to the emergency use, which are required to be made available as set forth in the Conditions of Authorization (Section IV), are collectly referred to as "authorized labeling":

- Fact Sheet for Healthcare Providers: Roche Molecular Systems, Inc.- cobas SARS-CoV-2
- Fact Sheet for Patients: Roche Molecular Systems, Inc.- cobas SARS-CoV-2

The above described product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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 your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your 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 your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), 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 your product, when used consistent with the Scope of Authorization of this letter (Section II), meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product 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) of the Act, described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for the cobas SARS-CoV-2 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 your product, but excluding Subpart

H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Roche Molecular Systems, Inc. (You) and Authorized Distributor(s) [10]

A. Your product must comply with the following labeling requirements under FDA regulations: 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)); 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).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) must include a physical copy of the authorized PIC card with each shipped product to authorized laboratories, and will make the authorized Instructions for Use electronically available with the opportunity to request a copy in paper form, and after such request, you must promptly provide the requested information without additional cost.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and the authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which you becomes aware.

H. You and authorized distributor(s) are authorized to make available additional

[10] "Authorized Distributor(s)" are identified by you, Roche Molecular Systems, Inc., in your EUA submission as an entity allowed to distribute your product.

information relating to the emergency use of the authorized cobas SARS-CoV-2 test that is consistent with, and does not exceed, the terms of this letter of authorization.

Roche Molecular Systems, Inc. (You)

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must 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).

K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

L. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to FDA and FDA's review and concurrence with the data, you will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must evaluate the clinical performance of your product to support the testing of individuals without symptoms or other reasons to suspect COVID-19 in an FDA agreed

[11] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

upon post authorization clinical evaluation study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must have a process in place to will track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803.

Authorized Laboratories

R. Authorized laboratories using your product must include with result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

S. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to perform the cobas SARS-CoV-2 test are not permitted.

T. Authorized laboratories that receive you product must notify the relevant public health authorities of their intent to run the test prior to initiating testing.

U. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

V. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with negative test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."

W. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Use of pooling based on prevalence" and "Monitoring plan for use of pooling" recommendations available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

X. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.

Y. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (Roche Diagnostics US Customer Technical Support 1-800-526-1247) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

Z. All laboratory personnel using the test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

Roche Molecular Systems, Inc. (You), Authorized Distributor(s), and Authorized Laboratories

AA. You, authorized distributor(s) and authorized laboratories using the cobas SARS-CoV-2 test must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

BB. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

CC. No descriptive printed matter, advertising, or promotional materials, relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

DD. All descriptive printed matter, advertising, and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product 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 and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure