U.S. FOOD & DRUG ADMINISTRATION

May 15, 2020

Frank S. Ong, MD, CPI
Chief Scientific and Medical Officer
Everlywell, Inc.
823 Congress Avenue,
Austin, TX 78701

Device:	Everlywell COVID-19 Test Home Collection Kit
Company:	Everlywell, Inc.
Indication:	For use by individuals to self-collect nasal swab specimens at home, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire, and for use only with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with the Everlywell COVID-19 Home Collection Kit.
Authorized Laboratories:	Testing is limited to laboratories designated by Everlywell, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests and that run the specimens collected from the Everlywell COVID-19 Test Home Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit for self-collection of nasal swab specimens.

Dear Dr. Ong:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Everlywell, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the Everlywell COVID-19 Test Home Collection Kit used for the indication identified above.

involves the virus that causes COVID-19.[3] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[4]

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, described in the Scope of Authorization 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 your product 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;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[5]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a home collection kit intended to facilitate self-collection of nasal swab specimens at home by individuals when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire. Once collected, the human specimen, which may include SARS-CoV-2 RNA, is maintained in the collection kit packaging during transport at ambient temperature to an authorized laboratory that runs the specimen on an authorized IVD molecular test for the detection of the virus that causes COVID-19 and is authorized for use with

[3] 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).
[4] U.S. Department of Health and Human Services, *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 17335 (March 27, 2020)
[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

the Everlywell COVID-19 Test Home Collection Kit. When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The Everlywell COVID-19 Test Home Collection Kit includes the following materials or other authorized materials: poly mailer, 2D barcode label, nasal swab, transport medium kit, kit ID stickers, return box, UN3373 label, medium alcohol prep pad, absorbent sheet, small biohazard bag, inner box tray, help and contact number insert, shipping and preparation instructions, self-collection instructions, welcome panel with kit ID, white tray, and return shipping label.

The above described product, is authorized to be accompanied with authorized labeling (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations). Authorized labeling includes the following documents: EUA Summary, Everlywell COVID-19 Test Home Collection Kit Instructions, COVID-19 Questionnaire (Screening SOP), and the Receiving and Processing Everlywell Samples standard operating procedure.

The above described product, when accompanied by the authorized labeling (identified above) is authorized to be distributed to and used by individuals and authorized laboratories as set forth in this letter and pursuant to the conditions in 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 authorized product, when used to diagnose COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product for such use.

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 your product may be effective in diagnosing COVID-19 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen when used consistently 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 (as described in 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product 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.

IV. Conditions of Authorization

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

Everlywell, Inc. (You) and Authorized Distributor(s)[6]

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)); 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) will make available on your website(s) the Everlywell COVID-19 Test Home Collection Kit Instructions.

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

D. Through a process of inventory control, you and authorized distributor(s) will maintain records of the numbers and locations to which your product is distributed .

E. You and authorized distributor(s) will maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Everlywell, Inc. (You)

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

[6] "Authorized Distributor(s)" are identified by you, Everlywell, Inc., in your EUA submission as an entity allowed to distribute your device.

H. You will notify FDA of any authorized laboratories designated by Everlywell, Inc. to use your product, including the name, address, and phone number of any authorized laboratories.

I. You will provide authorized distributor(s) and authorized laboratories with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You may request 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. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

K. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

L. You may request the addition and/or substitution of the components of the Everlywell COVID-19 Test Home Collection Kit. Such requests will be made by you in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH

M. You will track adverse events associated with the Everlywell COVID-19 Test Home Collection Kit, including occurrences of false results, and report to FDA under 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

N. You will make available all instructions related to the self-collection of nasal swab specimens at home using the Everlywell COVID-19 Test Home Collection Kit, both in the shipped kit and on your website.

O. You will notify FDA of any changes to the COVID-19 questionnaire used by a healthcare provider to determine eligibility of an individual to receive the Everlywell COVID-19 Test Home Collection Kit.

P. You will conduct a brief customer survey about the usability of the Everlywell COVID-19 Test Home Collection Kit and include results in the summary report outlined in Condition Q.

Q. You will submit to FDA a summary report within 30 calendar days of this letter summarizing the results of any testing performed using nasal specimens collected with

the Everlywell COVID-19 Test Home Collection Kit during that timeframe, including how many kits were requested and sent for home collection to individuals, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first Everlywell COVID-19 Test Home Collection Kit lot.

Authorized Laboratories

R. Authorized laboratories testing nasal swab specimens self-collected using the using the Everlywell COVID-19 Test Home Collection Kit must follow the Receiving and Processing Everlywell Samples standard operating procedure when accepting specimens for testing.

S. Authorized laboratories using your product will use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are authorized for use with home collection kits for self-collection of nasal swab specimens, including the Everlywell COVID-19 Test Home Collection Kit.

T. Authorized laboratories will 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 (via email: covidsupport@everlywell.com or 512-309-5588) any suspected occurrence of false positive or false negative results linked to use of your product and significant deviations from the established performance characteristics of your product of which they become aware.

Everlywell, Inc. (You), Authorized Distributors and Authorized Laboratories

U. You, authorized distributors, and authorized laboratories using your product will 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

V. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

W. No descriptive printed matter, including 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.

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

- This home collection kit has not been FDA cleared or approved;

- This home collection kit has been authorized by FDA under an EUA;
- This home collection kit has been authorized only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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 medical devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures