receive comments on the draft guidance. The guidance announced in this notice finalizes the draft guidance dated July 2022.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Impurities: Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision 2).'' 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 the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669; the collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov.*

Dated: July 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16408 Filed 7–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0150]

Revocation of Authorization of Emergency Use of In Vitro Diagnostic Device for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) (the Authorization) issued to Mesa Biotech Inc., (a legal entity of Thermo Fisher Scientific), for the Accula SARS–CoV–2 Test. FDA revoked the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by the Authorization holder. The revocation, which includes an explanation of the reasons for revocation, is reprinted at the end of this document.

DATES: The revocation of the Authorization for the Mesa Biotech Inc.'s Accula SARS–CoV–2 Test is effective as of May 22, 2024.

ADDRESSES: Submit written requests for a single copy of the revocation to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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 revocation may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocation.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (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, radiological, or nuclear agent or 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.

On March 23, 2020, FDA issued the Authorization to Mesa Biotech Inc. (a legal entity of Thermo Fisher Scientific), for the Accula SARS–CoV–2 Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act.

Subsequent updates to the Authorization were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Request

In a request received by FDA on May 15, 2024, Mesa Biotech Inc. (a legal entity of Thermo Fisher Scientific), made by Thermo Fisher Scientific, Inc. on behalf of Mesa Biotech Inc., requested the revocation of, and on May 22, 2024, FDA revoked, the Authorization for the Mesa Biotech Inc.'s Accula SARS–CoV–2 Test. Because Mesa Biotech Inc., notified FDA that they discontinued the commercialization of the Accula SARS–CoV–2 Test and requested FDA revoke Mesa Biotech Inc.'s Accula SARS–CoV–2 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at *https://www.regulations.gov/.*

IV. The Revocation

Having concluded that the criteria for revocation of the Authorization under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUA of Mesa Biotech Inc.'s Accula SARS–CoV–2 Test. The revocation in its entirety follows and provide an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

May 22, 2024

Anita Targosz
Senior Director, Quality
Thermo Fisher Scientific
5823 Newton Drive
Carlsbad, CA, 92008
Re: Revocation of EUA200028

Dear Anita Targosz:

This letter is in response to the request from Mesa Biotech Inc. (a legal entity of Thermo Fisher Scientific), made by Thermo Fisher Scientific, Inc. on behalf of Mesa Biotech Inc. in a letter dated May 15, 2024, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Accula SARS-CoV-2 Test issued on March 23, 2020, amended on April 30, 2020 and August 30, 2020, reissued on January 7, 2021, amended on February 3, 2021 and September 23, 2021, and reissued on May 16, 2022, August 17, 2022 and March 15, 2023. Thermo Fisher Scientific Inc. indicated that they have discontinued commercialization and support of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable Accula SARS-CoV-2 Test reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Mesa Biotech Inc., through Thermo Fisher Scientific, Inc., has requested that FDA revoke the EUA for the Accula SARS-CoV-2 Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200028 for the Accula SARS-CoV-2 Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Accula SARS-CoV-2 Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Dated: July 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16345 Filed 7–24–24; 8:45 am]

BILLING CODE 4161–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2980]

Evaluating the Immunogenicity Risk of Host Cell Proteins in Follow-On Recombinant Peptide Products; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is establishing a public docket to collect information and comments on evaluating and mitigating the immunogenicity risk of host cell proteins (HCPs). For the purpose of this request, FDA is specifically interested in comments on suitable methods to detect, identify, and quantify HCPs, on achievable residual amounts of HCPs for recombinant peptide products, and on the use of in vitro, in silico immunogenicity assessment (IVISIA) of HCPs in a recombinant peptide (rPeptide) product. For the purpose of this request, a ''follow-on'' peptide product refers to the applications currently evaluated through the 505(b)(2) pathway. Although follow-on recombinant peptide products can rely on FDA's findings of safety and effectiveness for a listed drug that is a peptide product, differences in recombinant expression systems used during the peptide production could result in quality attribute differences, including in the HCP profile, which in turn, could contribute to differences in immunogenicity risks between a follow-on recombinant peptide product and the listed drug. The public comments collected will help FDA develop recommendations on how HCP control and characterization can support comparative immunogenicity risk assessment between a recombinant follow-on peptide and the listed product.