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]
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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.

DATES: Although you can submit comments and information at any time, to ensure that the Agency considers your comment in our development of recommendations, submit either electronic or written information and comments by September 23, 2024.

ADDRESSES:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2980 for ''Evaluating the Immunogenicity Risk of Host Cell Proteins in Follow-On Recombinant Peptide Products; Establishment of a Public Docket; Request for Information and Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Mohsen Rajabiabhari, Office of Clinical Pharmacology, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–2794.

SUPPLEMENTARY INFORMATION:

I. Background

FDA for purposes of this notice uses the term ''peptide'' to refer to alpha amino acid polymers composed of 40 or fewer amino acids.[1] Peptides can be isolated from natural sources or produced synthetically or through recombinant expression in a host cell. Peptides that are isolated from recombinant (*i.e.,* genetically-modified) prokaryotic or eukaryotic host cells using cell culture/fermentation techniques are called recombinant peptides (rPeptides).

HCPs are process-related impurities derived from the host cell that may copurify with the recombinant peptide of interest and be present in the final drug product. HCPs are characterized and routinely well controlled during manufacturing of the peptide product. The types and amounts of HCPs in a product differ depending on many parameters, including differences in the expression cell substrate, culture conditions, the purification process, and amongst different facilities. Therefore, for a proposed follow-on rPeptide product, differences in HCP profiles between the follow-on product and the listed drug would be expected, and such differences have the potential to impact the safety and/or efficacy of the follow-on product by increasing that product's immunogenicity risk. Advances in technology may support the use of IVISIA methods to assess comparative immunogenicity risk.

II. Request for Information and Comments

Interested persons are invited to provide detailed information (including any supportive data) and comments on suitable methods to detect, identify, and quantify HCPs and the minimal residual amounts of HCPs achievable in commercial lots of rPeptide products. Specifically, to assess the potential impact of HCP differences, FDA is interested in responses to the following questions:

1. What is the lowest and routinely achievable level of total HCPs across your well-controlled rPeptide manufacturing process(es), and how are they calculated/established?
2. What are the challenges in reducing HCP levels?
3. What analytical methods are currently being used to detect, identify, and quantify HCPs in a rPeptide product? Do you conduct comparative assessments of HCPs, such as ELISA (enzyme-linked immunosorbent assay) vs LC/MS/MS (liquid chromatography tandem mass spectrometry), during manufacturing development? What is the sensitivity of these methods for detecting HCPs and their limits of quantification? Are you using a combination of orthogonal analytical methods (such as ELISA + LC/MS/MS) for HCP control during process development and manufacturing?

[1] See, *e.g.,* FDA Final Rule ''Definition of the Term 'Biological Product' '' (85 FR 10057, March 23, 2020).

4. What is the generally achievable percent coverage [2] of the HCP spectrum for your HCP quantification assay? What considerations, (*e.g.,* percent coverage of HCPs, other coverage characteristics, etc.), are important in choosing methods to evaluate HCPs?

5. Are there any qualitative or quantitative characteristics of HCPs associated with a higher likelihood of adverse clinical sequelae?

6. What tools (in silico, in vitro or in vivo studies) do you currently use or plan to use to compare the potential immunogenicity risk of two products with different HCP profiles? What is your approach to risk assessment of HCPs based upon such data?

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.

III. Electronic Access

Persons with access to the internet may obtain relevant guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacology-considerations-peptide-drug-products.*

Dated: July 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16356 Filed 7–24–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3228]

Biosimilar Product Development Guidance; 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 announcing the establishment of a docket to obtain information and comments that will assist the Agency in assessing how best to advance the development of new biosimilar biological products (biosimilars or biosimilar products), as part of the Biosimilar User Fee Amendments of 2022 (BsUFA III). As FDA continues to advance the development of biosimilars, we are seeking input from industry on whether biosimilar product development would be best served by focusing on product class-specific guidance documents that address common development issues that apply to a broad class of products, or by developing product-specific guidance documents, similar to the approach taken in the Generic Drug User Fee Amendments (GDUFA) program.

DATES: Submit either electronic or written comments, data, or information by October 23, 2024.

ADDRESSES: You may submit data, information, and comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 23, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3228 ''Biosimilar Product Development Guidance; Establishment of a Public Docket; Request for Information and Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the

[2] HCP coverage is an estimate of the percentage of HCPs specific to a cell substrate detected or covered by the capture antibodies of the ELISA. This coverage analysis is often done using 2D techniques.