

### G. Subpart R—Enforcement Procedures

We have determined that the ASHI meets the requirements of subpart R to the extent that it applies to accreditation organizations. The ASHI policy sets forth the actions the organization takes when laboratories it accredits do not comply with its requirements and standards for accreditation. When appropriate, the ASHI will deny, suspend, or revoke accreditation in a laboratory accredited by the ASHI and report that action to us within 30 days. The ASHI also provides an appeals process for laboratories that have had accreditation denied, suspended, or revoked.

We have determined that the ASHI's laboratory enforcement and appeal policies are equal to or more stringent than the requirements of part 493 subpart R as they apply to accreditation organizations.

### IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of laboratories accredited by the ASHI may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (that is, complaint inspections). The outcome of those validation inspections, performed by CMS or our agents, or the State survey agencies, will be our principal means for verifying that the laboratories accredited by the ASHI remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

### V. Removal of Approval as an Accrediting Organization

CLIA regulations at § 493.575 provide that we may rescind the approval of an accreditation organization, such as that of the ASHI, before the end of the effective date of approval in certain circumstances. For example, if we determine that the ASHI has failed to adopt, maintain and enforce requirements that are equal to, or more stringent than, the CLIA requirements, or that systemic problems exist in its monitoring, inspection or enforcement processes, we may impose a probationary period, not to exceed 1 year, in which the ASHI would be allowed to address any identified issues. Should the ASHI be unable to address the identified issues within that timeframe, CMS may, in accordance with the applicable regulations, revoke the ASHI's deeming authority under CLIA.

Should circumstances result in our withdrawal of the ASHI's approval, we

will publish a notice in the **Federal Register** explaining the basis for removing its approval.

### VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget (OMB) under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. Chapter 35). The requirements associated with the accreditation process for clinical laboratories under the CLIA program, codified in 42 CFR part 493 subpart E, are currently approved by OMB under OMB approval number 0938–0686.

### VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: April 12, 2022.

**Lynette Wilson,**

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2021–D–1238]

### Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.” This draft guidance addresses FDA's recommendations regarding clinical trials for drugs being developed

for the treatment of celiac disease as an adjunct to a gluten-free diet in adults.

**DATES:** Submit either electronic or written comments on the draft guidance by June 14, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### 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–2021–D–1238 for “Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.” Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY**

**INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Richard Whitehead, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3362, Silver Spring, MD 20993-0002, 301-796-4945; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.” This guidance addresses FDA’s current recommendations on clinical trials for drugs being developed for the treatment of celiac disease as an adjunct to a gluten-free diet in adults, including recommendations for eligibility criteria, trial design features, efficacy evaluations, clinical outcome assessments, and safety assessments.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.” 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 58, 21 CFR parts 312 and 314, and 21 CFR part 601 have been approved under OMB control numbers 0910-0130, 0910-0014, 0910-0001, and 0910-0338 respectively.

##### **III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/>

[regulatory-information/search-fda-guidance-documents](https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics), <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, or <https://www.regulations.gov>.

Dated: April 11, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA-2018-D-4367]

#### **Bioavailability Studies Submitted in NDAs or INDs—General Considerations; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Bioavailability Studies Submitted in NDAs or INDs—General Considerations.” This guidance provides recommendations to sponsors planning to include bioavailability (BA) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This guidance finalizes the draft guidance of the same title issued on February 26, 2019. This guidance also replaces the draft guidance entitled “Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations” issued March 2014.

**DATES:** The announcement of the guidance is published in the **Federal Register** on April 15, 2022.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

##### *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