

refused for filing because it is incomplete. This guidance includes procedures for certain BLAs and supplemental BLAs, given that CDER has regulatory responsibility for certain therapeutic biological products subject to licensing under the Public Health Service Act.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on refusal to file NDA and BLA submissions to CDER. 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. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26791 Filed 12–12–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5925]

21st Century Cures Act: Announcing the Establishment of the Susceptibility Test Interpretive Criteria Website

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of

the Susceptibility Test Interpretive Criteria Website. The Susceptibility Test Interpretive Criteria Website will help to efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health and may allow for more efficient development and evaluation of antimicrobial susceptibility test (AST) devices. These changes may lead to better patient care and reduce antimicrobial resistance through improved antibiotic stewardship. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

FOR FURTHER INFORMATION CONTACT:

Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182, Katherine.Schumann@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial susceptibility testing is used to determine if certain microorganisms that are isolated from a patient with an infection are likely to be killed or inhibited by a particular antimicrobial drug. It is important that the in vitro susceptibility test methods and susceptibility test interpretive criteria for systemic antibacterial or antifungal drugs be reviewed on a regular basis and updated to reflect the most current information. The development of new mechanisms of resistance in bacteria or fungi may result in decreased susceptibility to a particular drug. Decreased susceptibility may raise efficacy or safety concerns when out-of-date susceptibility test interpretive criteria are used in guiding the treatment of patients.

Historically, susceptibility test interpretive criteria have been contained in the Microbiology subsection of antimicrobial drug labeling, and there have been significant challenges associated with ensuring that this information is up-to-date in individual antimicrobial drug labels. For some time, FDA and other stakeholders have recognized that susceptibility test interpretive criteria standards established by nationally or internationally recognized standard development organizations (SDOs) can be useful sources of information to identify and update susceptibility test interpretive criteria.

Section 511A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360a–2), as added by section 3044 of the Cures Act (Pub. L. 114–255),

was signed into law on December 13, 2016. This provision clarifies FDA's authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards established by SDOs. It also clarifies that sponsors of AST devices may rely upon listed susceptibility interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which provides for a more streamlined process for incorporating up-to-date information into such devices.

II. Susceptibility Test Interpretive Criteria Website

Section 511A of the FD&C Act requires FDA to establish within 1 year after the date of enactment of the Cures Act an Interpretive Criteria Website that contains a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. FDA is announcing the establishment of this Interpretive Criteria Website, which can be found here: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm>.

This website recognizes susceptibility test interpretive criteria established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the FD&C Act; identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria listed by FDA on the Interpretive Criteria Website are deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)).

At least every 6 months after the establishment of the Interpretive Criteria Website, FDA will publish on the Interpretive Criteria Website a notice recognizing new or updated susceptibility test interpretive criteria standards, or parts of standards; withdrawing recognition of susceptibility test interpretive criteria standards, or parts of standards; and making any other necessary updates to the lists published on the Interpretive Criteria Website. Once a year FDA will compile the notices from that year and publish them in the **Federal Register** and provide for public comment. If comments are received, FDA will review those comments and make any updates to the recognized standards or susceptibility test interpretive criteria as

needed. In addition to this statutorily required annual notice, FDA intends to publish a **Federal Register** notice within the next few months to allow for public comment on the initial recognition of susceptibility test interpretive criteria.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-26790 Filed 12-12-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-D-6352]

Gluten in Drug Products and Associated Labeling Recommendations; 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 “Gluten in Drug Products and Associated Labeling Recommendations.” This draft guidance is intended to convey to drug manufacturers FDA’s recommendations on how certain oral drug products should be labeled regarding gluten, a matter of interest to individuals with celiac disease. Some individuals with celiac disease have faced difficulty when trying to determine whether specific drug products contain gluten. This draft guidance encourages drug manufacturers to have accurate information about their products’ gluten content available so they can respond to questions from consumers and health care professionals.

DATES: Submit either electronic or written comments on the draft guidance by February 12, 2018 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-2017-D-6352 for “Gluten in Drug Products and Associated Labeling Recommendations.” 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.

- **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.gpo.gov/fdsys/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.

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 to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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:

Marci Kiester, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2258, Silver Spring, MD 20993-0002, 301-796-0600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Gluten in Drug Products and Associated Labeling