**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2023–22809 Filed 10–16–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–D–2016]**

### Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol; 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 ''Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol.'' This guidance is intended to alert pharmaceutical manufacturers and pharmacists in State-licensed pharmacies or Federal facilities who engage in drug compounding to the potential public health hazard of alcohol (ethyl alcohol or ethanol) or isopropyl alcohol contaminated with or substituted with methanol. During the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE), FDA became aware of reports of fatal methanol poisoning of consumers who ingested alcohol-based hand sanitizer products that were manufactured with methanol or methanol-contaminated ethanol. FDA is concerned that other drug products containing ethanol or isopropyl alcohol (pharmaceutical alcohol), which are widely used active ingredients in a variety of drug products, could be similarly vulnerable to methanol contamination. This guidance replaces the guidance for industry entitled ''Policy for Testing Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID–19)'' published in January 2021.

**DATES:** The announcement of the guidance is published in the **Federal Register** on October 17, 2023.

**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 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–2020–D–2016 for ''Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol.'' 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 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; or to Policy and Regulations Staff, HFV–6, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Francis Godwin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4342, Silver Spring, MD 20993–0002, 301–796–5362; or Anne Taylor, 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; or Julie Bailey, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0700.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol.'' This guidance is intended to alert pharmaceutical manufacturers and pharmacists in State-licensed pharmacies or Federal facilities who engage in compounding to the potential public health hazard of alcohol (ethyl alcohol or ethanol) or isopropyl alcohol (collectively ''pharmaceutical alcohol'') contaminated with or substituted with methanol. During the COVID–19 PHE, FDA became aware of reports of fatal methanol poisoning of consumers who ingested alcohol-based hand sanitizer products that were manufactured with methanol or methanol-contaminated ethanol. FDA is concerned that other drug products containing pharmaceutical alcohol, which are widely used active ingredients in a variety of drug products, could be similarly vulnerable to methanol contamination.

This guidance outlines a policy intended to help pharmaceutical manufacturers and pharmacists in State-licensed pharmacies or Federal facilities who engage in compounding avoid the use of pharmaceutical alcohol that is contaminated with or substituted with methanol in drug products. The policy outlined in the guidance includes, but is not limited to: (1) performing a specific identity test that includes a limit test for methanol on each container within each shipment of each lot of pharmaceutical alcohol before the component is used in the manufacture or preparation of drug products; (2) knowing the entities in pharmaceutical manufacturers' supply chain for pharmaceutical alcohol (*i.e.,* knowing the identities and appropriately qualifying the manufacturer of the pharmaceutical alcohol and any subsequent distributor(s)); (3) ensuring that all personnel in pharmaceutical manufacturing facilities (especially personnel directly responsible for receipt, testing, and release of pharmaceutical alcohol) are made aware of the importance of proper testing and the potential hazards if the testing is not done; and (4) establishing finished-product test methods to ensure that when testing for ethanol or isopropyl alcohol content (assay), the method also distinguishes between the active ingredient and methanol. The policy outlined in this guidance applies to pharmaceutical alcohols used as an active or inactive ingredient in a drug.

This guidance replaces the guidance entitled ''Policy for Testing Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID–19)'' posted in January 2021 and announced in the **Federal Register** on February 23, 2021 (86 FR 10977) (hereafter ''2021 COVID–19 Methanol Guidance''). FDA issued the guidance to communicate its policy for the duration of the COVID–19 PHE declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). As stated in the 2021 guidance, at such time when the PHE was over, as declared by the HHS Secretary, FDA intended to reassess the guidance. Furthermore, in the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed the guidance documents that will no longer be effective with the expiration of the PHE declaration, guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration to provide a period for stakeholder transition and then would no longer be in effect, and guidances that FDA was revising to continue in effect for 180 days after the expiration of the PHE declaration during which time FDA planned to further revise the guidances. The 2021 COVID–19 Methanol Guidance is included in the latter category. Although the COVID–19 PHE ended May 11, 2023, FDA has determined that the recommendations set forth in the 2021 COVID–19 Methanol Guidance are applicable outside the context of the COVID–19 PHE. FDA is, therefore, issuing this revised final guidance, which will supersede the current guidance. In preparing this guidance, FDA considered comments received regarding the 2021 guidance, as well as the Agency's experience with this matter during the PHE. Updates to this guidance include removal of certain language regarding the COVID–19 PHE, as well as removal of language related to the three hand sanitizer guidance documents that have since been withdrawn.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115 (21 CFR 10.115)) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because, although the COVID–19 PHE has ended, the use of hand sanitizers and other drug products containing pharmaceutical alcohol remains widespread. Given the serious risks to public health, including blindness and death, that can result from methanol contamination, it is thus important to public health to continue to apply the policy described in the guidance, which encourages stringent and continued oversight of such products for the possible presence of methanol.

The guidance represents the current thinking of FDA on ''Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol.'' 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 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: October 11, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–22843 Filed 10–16–23; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–P–3682]**

### Determination That ZOFRAN ODT (Ondansetron) Orally Disintegrating Tablets, 4 Milligrams and 8 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined that ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 milligrams (mg) and 8 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

**FOR FURTHER INFORMATION CONTACT:** Veniqua Stewart, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6219, Silver Spring, MD 20993–0002, 301–796–3267, *Veniqua.stewart@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, are the subject of NDA 020781, held by Sandoz Inc., and initially approved on January 27, 1999. ZOFRAN ODT is indicated for the prevention of nausea and vomiting associated with: highly emetogenic cancer chemotherapy, including cisplatin greater than or equal to 50 mg/m$^2$; initial and repeat courses of moderately emetogenic cancer chemotherapy; and radiotherapy in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen. ZOFRAN ODT is also indicated for the prevention of postoperative nausea and/or vomiting.

ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Sun Pharmaceutical Industries Limited submitted a citizen petition dated August 24, 2023 (Docket No. FDA–2023–P–3682), under 21 CFR 10.30, requesting that the Agency determine whether ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, were not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 mg and 8 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 10, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–D–4067]**

### Diabetic Foot Infections: Developing Drugs for Treatment; 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 ''Diabetic Foot Infections: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist sponsors in the