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Determination That ZOFRAN ODT (Ondansetron) Orally Disintegrating Tablets, 4 Milligrams and 8 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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has determined that ZOFRAN ODT (ondansetron) orally disintegrating tablets, 4 milligrams (mg) and 8 mg, were not withdrawn from sale for reasons of safety or effectiveness.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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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.

[FR Doc. 2023–22844 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–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

clinical development of drugs for the treatment of diabetic foot infections (DFI) without concomitant bone and joint involvement.

DATES: Submit either electronic or written comments on the draft guidance by December 18, 2023 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–2023–D–4067 for ''Diabetic Foot Infections: Developing Drugs for Treatment.'' 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. 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: Mayurika Ghosh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6219, Silver Spring, MD 20993, 301–796–4776.

SUPPLEMENTARY INFORMATION:

I. Background

FDA 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 clinical development of drugs for the treatment of DFI without concomitant bone and joint involvement. Specifically, this guidance addresses FDA's current thinking regarding the overall development program and clinical trial designs for the development of drugs to support an indication for treatment of DFI.

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 ''Diabetic Foot Infections: Developing Drugs for Treatment.'' 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 201.56 and 201.57 relating to prescription product labeling requirements have been approved under OMB control number 0910–0572.

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*, or *https://www.regulations.gov*.

Dated: October 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22842 Filed 10–16–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Rural Health and Economic Development Analysis Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Announcing funding supplement for Rural Health and Economic Development Analysis Program.

SUMMARY: HRSA provided additional award funds to the Rural Health and Economic Development Analysis Program recipient to produce a research project that quantifies the relationships between health care and economic factors in rural communities.

FOR FURTHER INFORMATION CONTACT: Karis Tyner, Federal Office of Rural Health Policy, HRSA, at *ktyner@hrsa.gov* and (240) 645–5756.

SUPPLEMENTARY INFORMATION:

TABLE 1—RECIPIENT AND AWARD AMOUNT

Grant No.	Award recipient name	City, state	Supplemental award amount
5 U1ZRH33331	The University of Kentucky	Lexington, KY	$250,000

Intended Recipient of the Award: The University of Kentucky.

Amount of Non-Competitive Award: One award for $250,000.

Project Period: September 1, 2023, to August 31, 2024.

CFDA Number: 93.155.

Award Instrument: Supplement.

Authority: Social Security Act section 711(b) (42 U.S.C. 912(b)).

Justification: This funding will provide a one-time supplement to the University of Kentucky via the Rural Health and Economic Development Analysis Program with a budget period of September 2023 through August 2024. This supplement will allow the University of Kentucky to build on past and ongoing projects supported by HRSA to improve health care in rural areas by advancing the knowledge base regarding the economic impacts of local health care sectors on rural economies.

Carole Johnson,

Administrator.

[FR Doc. 2023–22814 Filed 10–16–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Healthy People 2030 Objectives

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary of Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) solicits written comments from the public on the current Healthy People 2030 objectives, and written comments from the public proposing additional new core, developmental, or research objectives or topics to be included in Healthy People 2030. Public comment informed the development of Healthy People 2030. HHS will provide opportunities for public input periodically throughout the decade to ensure Healthy People 2030 reflects current public health priorities and public input. The updated set of Healthy People 2030 objectives and topics will be incorporated on *https://health.gov/healthypeople.* This updated set will reflect further review and deliberation by Federal Healthy People topic area workgroups, the Federal Interagency Workgroup on Healthy People 2030, and other Federal subject matter experts.

DATES: Written comments will be accepted through 11:59 p.m. ET, November 20, 2023.

ADDRESSES: Written comments should be submitted by email to *HP2030Comment@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Erik Orta, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240–268–0823; Email: *HP2030@hhs.gov.*

SUPPLEMENTARY INFORMATION: Since 1980, Healthy People has provided a comprehensive set of national health promotion and disease prevention objectives with 10-year targets aimed at improving the health of all. Healthy People 2030 objectives present a picture of the nation's health at the beginning of the decade, establish national goals and targets to be achieved by the year 2030, and monitor progress over time. The U.S. Department of Health and Human Services (HHS) is soliciting the submission of written comments regarding the current Healthy People 2030 objectives. The public is also invited to submit proposals for additional new core, developmental, or research objectives that meet the criteria outlined below.

Healthy People 2030 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the Federal Government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2030's development. During the first phase of planning for Healthy People 2030, HHS asked for the public's comments on the initiative's vision, mission, and overarching goals. Those comments helped set the framework for Healthy People 2030. The public was also invited to submit comments on proposed Healthy People 2030 objectives, which helped shape the current set of Healthy People 2030 objectives. HHS most recently solicited comments on one new objective during the 2022 public comment period from October 24, 2022, through December 2, 2022, and three new proposed objectives during the 2021 public comment period from December 3, 2021, through January 10, 2022. These new objectives, which were developed by Healthy People 2030 subject matter experts, meet specific criteria, and reflect public input, are now accessible on *https://health.gov/healthypeople.*

While there are no new objectives being proposed at this time, the public