4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidance; Revised Draft Guidance for Industry on Sucralfate; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for a revised draft product-specific guidance on Sucralfate that appeared in a notice of availability, published in the *Federal Register* of October 20, 2017. In that notice, FDA requested comments on the revised draft guidance for industry on Sucralfate, as well as comments on other product-specific guidances. FDA is reopening the comment period for the Draft Guidance on Sucralfate (revised October 2017) to facilitate submission of comments pertaining to this draft guidance following an FDA response to two citizen petitions. The petition response suggests that the petitioners submit to the docket comments relating to the guidance.

DATES: Submit either electronic or written comments on the draft guidance by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2007-D-0369 for "Product-Specific Guidance; Revised Draft Guidance for Industry on Sucralfate; Reopening of Comment Period." 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. 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: Xiaoqiu Tang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993-0002, 301-796-5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of October 20, 2017 (82 FR 48826), FDA published a notice of availability with a 60-day comment period to request comments on the revised draft guidance for industry on Sucralfate, as well as comments on other product-specific guidances. This draft guidance includes recommendations pertaining to abbreviated new drug applications seeking approval of sucralfate oral suspension products, 1 gram/10 milliliters.

The comment period for all draft guidances identified in that notice ended on December 19, 2017.

On December 18, 2017, FDA received a citizen petition from Haynes and Boone, LLP (Docket No. FDA-2017-P-6922), requesting that FDA deny approval to any abbreviated new drug application for a sucralfate oral suspension drug product that relies on patient-based clinical endpoint studies to establish bioequivalence with the reference listed drug. On March 28, 2018, FDA received a citizen petition from Vertice Pharma (Docket No. FDA-2018-P-1310) requesting specific changes to the recommendations made in the "Draft Guidance on Sucralfate" (revised October 2017), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM573202.pdf.

FDA denied both petitions in a joint response dated May 17, 2018. However, given the interest in this guidance, FDA is reopening the comment period until **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The Agency believes that an additional 60 days will allow adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

II. 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: October 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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