presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

Dated: August 16, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–20187 Filed 8–23–16; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1580]

Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling; Guidance for Industry, Food and Drug Administration Staff and Other Stakeholders; 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 the guidance entitled ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling.'' This document explains the principal concepts that sponsors and other stakeholders should consider when choosing to collect patient preference information (PPI), which may inform FDA's benefit-risk determinations in the premarket review of premarket approval applications (PMAs), humanitarian device exemption (HDE) applications, and *de novo* classification requests. This guidance also discusses FDA's inclusion of PPI in its decision summaries and provides recommendations for the inclusion of such information in device labeling for certain devices. FDA is also issuing a Level 2 updated version of the guidance document entitled ''Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications,'' originally issued on March 28, 2012, that has been edited to be consistent with this guidance document.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–D–1580 for ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling.'' If you are making submissions that also address the edits to the Level 2 guidance, the submissions received must include the Docket No. FDA–2011–D–0577 for ''Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications.'' Received comments will be placed in the docket(s) noted and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or 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 request.

FOR FURTHER INFORMATION CONTACT: Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5414, Silver Spring, MD 20993–0002, 301–796–2537, *Anindita.Saha@fda.hhs.gov;* 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling.'' FDA believes that patients can and should bring their own experiences to bear in helping the Agency to evaluate the benefit-risk profiles of certain devices. This kind of input can be important to consider during FDA's decisionmaking for these devices.

This document explains the principal concepts that sponsors and other stakeholders should consider when choosing to collect PPI, which may inform FDA's benefit-risk determinations in the premarket review of PMAs, HDE applications, and *de novo* requests. This guidance also discusses FDA's inclusion of PPI in its decision summaries and provides recommendations for the inclusion of such information in device labeling for certain devices.

The objectives of this guidance are: (1) To encourage submission of PPI, if available, by sponsors or other stakeholders to FDA and to aid in FDA decisionmaking; (2) to outline recommended qualities of patient preference studies, which may result in valid scientific evidence; (3) to provide recommendations for collecting and submitting PPI to FDA; and (4) to discuss FDA's inclusion of PPI in its decision summaries and provide recommendations for the inclusion of such information in device labeling, where appropriate. The guidance also includes hypothetical examples that illustrate how PPI may inform FDA's decisionmaking. The guidance applies to both diagnostic and therapeutic devices that are subject to these review processes. Additionally, this guidance may be information to other stakeholders such as patient groups and academia who may wish to conduct patient preference studies.

In the **Federal Register** of May 18, 2015 (80 FR 28277), FDA announced the availability of the draft of this guidance and interested persons were invited to comment by August 17, 2015. FDA has considered all of the public comments received in finalizing this guidance.

FDA is also issuing a Level 2 update to the guidance document entitled ''Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications,'' which was originally issued on March 28, 2012, to ensure consistency with the terminology and concepts presented in this guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling.'' 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryinformation/Guidances/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Patient Preference Information—Voluntary Submission, Review in PMAs, HDE Applications, and *De Novo* Requests, and Inclusion in Decision Summaries and Device Labeling'' or ''Factors To Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approval and *De Novo* Classifications'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500006 or 1772 respectively to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to currently approved collections of information found in FDA regulations. These collections of information 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 812.25(c) have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts B and E have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; the collections of information in 21 CFR part 822 have been approved under OMB control number 0910–0449; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; and the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: August 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–20221 Filed 8–23–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Fidaxomicin; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry on generic fidaxomicin tablets entitled ''Draft Guidance on Fidaxomicin.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for fidaxomicin tablets.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 24, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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 ''Draft Guidance on Fidaxomicin.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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 (HFD–600), 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 June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific BE recommendations and to provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of draft BE recommendations for generic fidaxomicin tablets.

FDA initially approved new drug application (NDA) 201699 for DIFICID (fidaxomicin) in May 2011. Currently, there are no approved ANDAs for this product. We are now issuing a draft guidance for industry on BE recommendations for generic fidaxomicin tablets (''Draft Guidance on Fidaxomicin'').

On May 6, 2015, Cubist Pharmaceuticals, Inc. submitted a