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). We note that the information collected under the underlying CGMP regulations for drugs, devices, and biological products, including current good tissue practices for HCT/Ps, found in parts 211, 820, 600 through 680, and 1271, have already been approved and are in effect. The provisions of part 211 are approved under the OMB control number 0910–0139. The provisions of part 820 are approved under OMB control number 0910–0073. The provisions of parts 606 and 640 are approved under OMB control number 0910–0116. The provisions of part 610 are approved under OMB control number 0910–0116 and OMB control number 0910–0338 (also for part 680). The provisions of part 1271, subparts C and D, are approved under OMB control number 0910–0543.

We note that the information collected under the related submission types have already been approved and are in effect. The collections of information regarding formal meetings with sponsors and applicants have been approved under OMB control number 0910–0429. The collections of information regarding new drug approvals (NDA) and abbreviated new drug applications (ANDA) have been approved under OMB control number 0910–0001. The collections of information regarding pre-ANDAs have been approved under OMB control number 0910–0797. The collections of information regarding pre-submissions have been approved under OMB control number 0910–0756. The collections of information regarding PMAs have been approved under OMB control number 0910–0231. The collections of information for premarket notification (510(k)) have been approved under OMB control number 0910–0120. The collections of information for the de novo classification process have been approved under OMB control number 0910–0844. The collections of information regarding biologics license applications have been approved under OMB control number 0910–0338.

VI. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. ''Guidance for Industry and FDA Staff: Current Good Manufacturing Practice Requirements for Combination Products,'' January 2017. *https://www.fda.gov/RegulatoryInformation/Guidances/ucm126198.htm.*
2. ''Guidance for Industry: Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products,'' January 2003. *https://www.fda.gov/downloads/Drugs/Guidances/ucm073379.pdf.*
3. ''Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products,'' December 2017. *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf.*
4. ''Draft Guidance for Industry: Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA,'' October 2017. *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm578366.pdf.*
5. ''Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff,'' September 2017. *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf.*
6. ''eCTD Technical Conformance Guide,'' November 2017. *https://www.fda.gov/downloads/Drugs/UCM465411.pdf.*
7. ''Guidance for Industry: Changes to an Approved NDA or ANDA,'' April 2004. *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm077097.pdf.*
8. ''Draft Guidance for Industry: Chemistry, Manufacturing, and Controls Changes to an Approved Application: Certain Biological Products,'' December 2017. *https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/UCM590118.pdf.*
9. ''Guidance for Industry and FDA Staff: 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes,'' April 2011. *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080194.pdf.*

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12634 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0223]

Humanitarian Device Exemption Program; Draft Guidance for Industry and Food and Drug Administration Staff; 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 draft guidance entitled ''Humanitarian Device Exemption (HDE) Program.'' This draft guidance concerns the HDE program as a whole and, among other topics, it explains the criteria FDA considers to determine if ''probable benefit'' has been demonstrated as part of the Agency's decision-making process regarding marketing authorization for a humanitarian use device (HUD). The draft guidance also incorporates recent amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that affect the HDE program and answers other common questions that we receive about the program. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 13, 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–2014–D–0223 for ''Humanitarian Device Exemption (HDE) Program.'' 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)).

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 draft guidance document entitled ''Humanitarian Device Exemption (HDE) Program'' 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: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1650, Silver Spring, MD 20993–0002, 301–796–6524; 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 developed this draft guidance to clarify to industry and FDA staff the current review practices for the HDE program. This draft guidance answers common questions about the HDE program and responds to a requirement in the 21st Century Cures Act (Cures Act, Pub. L. 114–255) to define the criteria for establishing ''probable benefit'' as that term is used in section 520(m)(2)(C) of the FD&C Act (21 U.S.C. 360j(m)(2)(C)).

This draft guidance incorporates recent amendments to the FD&C Act that affect the HDE program. Specifically, section 3052 of the Cures Act modified the eligibility for an HDE by increasing the threshold number of patients affected by the disease or condition that a HUD is designed to treat or diagnose to ''not more than 8,000 individuals in the United States.'' Further, section 3056 the Cures Act removed the requirement that institutional review committees, *i.e.,* institutional review boards (IRBs), that supervise the clinical testing of HUDs or approve the use of HUDs in clinical care be local.

Additionally, the FDA Reauthorization Act of 2017 (Pub. L. 115–52) amended section 520(m) of the FD&C Act to provide that the use of a device under an HDE at a facility to treat or diagnose patients may be approved by an IRB or an appropriate local committee. Previously, section 520(m)(4) of the FD&C Act only allowed an IRB to perform this function. FDA is providing an interpretation of the term ''appropriate local committee'' in this draft guidance, and we welcome comment on the characteristics that should define an appropriate local committee for purposes of the HDE program.

This draft guidance supplants the draft guidance, ''Humanitarian Device Exemption (HDE): Questions and Answers—Draft Guidance for HDE Holders, IRBs, Clinical Investigators, and Food and Drug Administration Staff,'' issued on March 18, 2014. When final, this guidance will supersede the guidance, ''Guidance for HDE holders, IRBs, Clinical Investigators, and Food and Drug Administration Staff, HDE Regulation: Questions and Answers,'' issued on July 8, 2010, available online at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM110203.*

II. Significance of Guidance

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 the Humanitarian Device Exemption Program. 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.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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.* This guidance document is also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Humanitarian Device Exemption (HDE) Program'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 17040 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 part 10 have been approved under OMB control number 0910–0191; the collections of information in 21 CFR parts 50 and 56 have been approved under OMB control numbers 0910–0755 and 0910–0130; the collections of information in 21 CFR part 54 have been approved under OMB control number 0910–0396; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 814, subparts A through 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 820 have been approved under OMB control number 0910–0073; the collections of information regarding Information to Accompany HDE Applications and Annual Distribution Number Reporting Requirements have been approved under OMB control number 0910–0661; and the collections of information in the guidance document ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

Dated: June 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12633 Filed 6–12–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–2032]

Limited Population Pathway for Antibacterial and Antifungal Drugs; 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 ''Limited Population Pathway for Antibacterial and Antifungal Drugs.'' This guidance provides information on the implementation of the limited population pathway provision of the 21st Century Cures Act (Cures Act), which established the limited population pathway for antibacterial and antifungal drugs (LPAD pathway).

DATES: Submit either electronic or written comments on the draft guidance by August 13, 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–2018–D–2032 for ''Limited Population Pathway for Antibacterial and Antifungal Drugs; Draft Guidance for Industry; Availability.'' 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