Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, 240–402–5118.

SUPPLEMENTARY INFORMATION:

I. Background

GDUFA (Pub. L. 112–144, Title III) was signed into law by the President on July 9, 2012. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and to improve the review process for ANDAs. GDUFA enables FDA to assess user fees to support critical and measurable enhancements to FDA's generic drugs program.

On August 27, 2012, FDA announced the availability of a draft guidance for industry entitled ''Generic Drug User Fee Amendments of 2012: Questions and Answers'' (77 FR 51814). On September 10, 2013, FDA announced the availability of a revised version of this guidance (78 FR 55261). The comment period on the revised draft guidance ended on December 11, 2013 (78 FR 70953). FDA received several comments on the draft guidance, and these comments as well as FDA's experience implementing GDUFA were considered as the guidance was finalized.

This guidance is intended to provide answers to common questions from generic drug industry participants and other interested parties involved in the development and/or testing of generic drug products regarding FDA's implementation of GDUFA. This guidance includes three categories of questions and answers: Self-identification of facilities, sites, and organizations; review of generic drug submissions; and inspections and compliance. The draft versions of this guidance also addressed the subject of fees. The portion of the draft guidance relating to fees was updated and finalized in November 2016 (81 FR 81774, November 18, 2016).

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 ''Generic Drug User Fee Amendments of 2012: Questions and Answers Related to Self-Identification of Facilities, Review of Generic Drug Submissions, and Inspections and Compliance.'' 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.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: July 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15654 Filed 7–25–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–3906]

Consumer Antiseptic Wash Final Rule Questions and Answers; Guidance for Industry; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled ''Consumer Antiseptic Wash Final Rule Questions and Answers.'' We are issuing this guidance in accordance with the Small Business Regulatory Enforcement Fairness Act to assist small businesses in better understanding and complying with the consumer antiseptic wash final rule, which established that certain active ingredients, including triclosan, used in over-the-counter (OTC) consumer antiseptic wash products are not generally recognized as safe and effective (GRASE). This guidance explains the scope of the final rule, how and when manufacturers must comply with the final rule, and which consumer antiseptic wash active ingredients were deferred from the final rule.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments 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–2017–D–3906 for ''Consumer Antiseptic Wash Final Rule Questions and Answers; Guidance for Industry; Small Entity Compliance Guide.'' 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.

Submit written requests for single copies of this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0272.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Consumer Antiseptic Wash Final Rule Questions and Answers.'' We are issuing this guidance in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121, as amended by Pub. L. 110–28) [1] to assist small businesses in better understanding and complying with the consumer antiseptic wash final rule (September 6, 2016, 81 FR 61106), which established that certain active ingredients used in OTC consumer antiseptic wash products are not GRASE. This guidance explains the scope of the final rule and identifies which active ingredients were found not to be GRASE for use in consumer antiseptic wash products. This guidance explains when and how manufacturers must comply with the final rule. This guidance also explains the significance of triclosan and triclocarban under this final rule. In addition, this guidance identifies which consumer antiseptic wash active ingredients were deferred from the final rule and explains what the effectiveness and safety criteria are for these deferred consumer antiseptic wash active ingredients.

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 how small businesses can better understand and comply with the consumer antiseptic wash final rule. 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.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: July 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15653 Filed 7–25–17; 8:45 am]

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[1] 5 U.S.C. 601 (note).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (PEAC). The general function of the committee is to provide advice and recommendations to the Agency on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public. This meeting will be the inaugural meeting of a new advisory committee.

DATES: The meeting will be held on October 11, 2017, from 1 p.m. to 5 p.m. and October 12, 2017, from 8 a.m. to 5 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301–977–8900. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On October 11 and 12, 2017, the committee will discuss and make recommendations on the topic of patient input into medical device clinical trials. This meeting will provide the opportunity to bring patients, patient organization, FDA, industry, and other medical and scientific experts together for a broader discussion on this important patient-related issue.

This meeting is a key part of FDA's goal to help assure the needs and experiences of patients are included as part of FDA's deliberations involving the regulation of medical devices and their use by patients. For this meeting, FDA is seeking input from the PEAC and the public on topics such as to: (1) Better understand challenges for patients in medical device clinical trials, (2) better understand how patient input and engagement is being used to overcome these challenges (potential solutions), and (3) receive