It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2016–01944 Filed 2–2–16; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR–2016–0001]

Availability of Draft Toxicological Profile; Glutaraldehyde

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for comment.

SUMMARY: This notice, prepared by the Agency for Toxic Substances and Disease Registry (ATSDR), announces the availability of the Toxicological Profile for Glutaraldehyde for review and comment. All toxicological profiles issued as ''Drafts for Public Comment'' represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information or reports on studies about the health effects of glutaraldehyde for review and potential inclusion in the profile.

Comments can include additional information or reports on studies about the health effects of glutaraldehyde. Although ATSDR will consider key studies for this substance during the profile development process, this **Federal Register** notice solicits any relevant, additional studies, particularly unpublished data. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion into the profile. ATSDR is providing a public comment period for this document as a means to best serve public health and our clients.

DATES: Written comments on this draft Toxicological Profile must be received on or before May 3, 2016.

ADDRESSES: You may submit comments, identified by docket number ATSDR–2016–0001, by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F–57, Atlanta, GA, 30329. Attn: Docket No. ATSDR–2016–0001.

Instructions: All submissions received must include the agency name and docket number for this notice. All relevant comments will be posted without change. Because all public comments regarding ATSDR Toxicological Profiles are available for public inspection, no confidential business information or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Delores Grant, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F–57, Atlanta, GA, 30329. Phone: (800) 232–4636 or 770–488–3351.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (U.S. EPA) regarding hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances [also called the Substance Priority List (SPL)]. This list identifies 275 hazardous substances that ATSDR (in cooperation with EPA) has determined pose the most significant potential threat to human health. The 2015 SPL is available online at *www.atsdr.cdc.gov/spl.*

In addition, ATSDR has the authority to prepare toxicological profiles for substances not found at sites on the National Priorities List, in an effort to ''establish and maintain inventory of literature, research, and studies on the health effects of toxic substances'' under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and as otherwise necessary to support the site-specific response actions conducted by ATSDR.

The public comments and other data submitted in response to the **Federal Register** notices are available for public inspection at ATSDR. Comments are available for public inspection from Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 4770 Buford Hwy NE., Atlanta, Georgia 30341. Please call ahead to 1–800–232–4636 and ask for a representative in the Division of Toxicology and Human Health Sciences to schedule your visit.

Availability

The Glutaraldehyde Toxicological Profile is available online at *http://www.atsdr.cdc.gov/toxprofiles/index.asp* and *www.regulations.gov*, Docket No. ATSDR–2016–0001.

Donna B. Knutson,

Acting Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry.

[FR Doc. 2016–01972 Filed 2–2–16; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4599]

List of Highest Priority Devices for Human Factors Review; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''List of Highest Priority Devices for Human Factors Review.'' FDA is issuing this draft guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions. FDA believes these device types have clear potential for serious harm resulting from use error and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices. This draft guidance is not final nor is it in effect at this time.

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 of 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 May 3, 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–2015–D–4599 for ''List of Highest Priority Devices for Human Factors Review.'' Received comments will be placed in the docket 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 draft guidance document entitled ''List of Highest Priority Devices for Human Factors Review'' 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. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shannon Hoste, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2531, Silver Spring, MD 20993–0002, 240–402–3747, or *shannon.hoste@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Human factors testing is a valuable component of product development for medical devices. FDA recommends that manufacturers consider human factors testing for medical devices as a part of a robust design control subsystem. This draft guidance, if finalized, will inform medical device manufacturers which device types should have human factors data included in premarket submissions (*i.e.,* for premarket approval 510(k)). FDA believes these device types have clear potential for serious harm resulting from use error and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document, ''Applying Human Factors and Usability Engineering to Medical Devices,'' to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses, and use environments. Devices that should include human factors data in premarket submissions are listed in this draft guidance. When and if this draft guidance is finalized, FDA recommends that for devices identified in the draft guidance, manufacturers should provide FDA with a report that summarizes the human factors or usability engineering processes they have followed, including any preliminary analyses and evaluations and human factors validation testing, results, and conclusions.

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 list of highest priority devices for human factors review. 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 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.*

Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''List of Highest Priority Devices for Human Factors Review'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500052 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. 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 820 are approved under OMB control number 0910–0073; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H are approved under OMB control number 0910–0332; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: January 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01889 Filed 2–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0429]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 4, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0731. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Meetings With Industry and Investigators on the Research and Development of Tobacco Products

OMB Control Number 0910–0731—Extension

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) offers tobacco product manufacturers several pathways to obtain an order from FDA to authorize the marketing of a new tobacco product before it may be introduced or delivered into interstate commerce. To provide assistance with these pathways to market products, FDA will meet with tobacco product manufacturers, importers, researchers, and investigators (or their representatives) when appropriate. This guidance is intended to assist persons who seek meetings with FDA relating to their research to inform the regulation of tobacco products, or to support the development or marketing of tobacco products. The guidance has been revised to provide clarity.

In the guidance, the Agency discusses, among other things:

- What information FDA recommends persons include in a meeting request;
- How and when to submit a request; and
- What information FDA recommends persons submit prior to a meeting.

This guidance describes two collections of information: (1) The submission of a meeting request containing certain information and (2) the submission of an information package in advance of the meeting. The purpose of this proposed information collection is to allow FDA to conduct meetings with tobacco manufacturers, importers, researchers, and investigators in an effective and efficient manner. FDA issued this guidance as a level 2 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115).

Meeting Requests: The guidance sets forth FDA's recommendations for materials to be included in a request for a meeting with FDA to discuss the research and development of tobacco products. In the guidance, FDA recommends that the following information be included in the meeting request:

1. Product name and FDA-assigned Submission Tracking Number (if applicable);
2. Product category (*e.g.,* cigarettes, smokeless tobacco) (if applicable);
3. Product use (indicate for consumer use or for further manufacturing);
4. Contact information for the authorized point of contact for the company requesting the meeting;
5. The topic of the meeting being requested (*e.g.,* a new tobacco product application, an application for permission to market an MRTP, or investigational use of a new tobacco product);
6. A brief statement of the purpose of the meeting, which could include a discussion of the types of studies or data to be discussed at the meeting, the general nature of the primary questions to be asked, and where the meeting fits in the overall product development plans;
7. A preliminary list of the specific objectives/outcomes expected from the meeting;