Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–26320 Filed 10–15–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3474]

Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft recommendations for a new permitted daily exposure (PDE) for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone, according to the maintenance procedures for the guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The draft recommendations were prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient.

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 the draft recommendations before it begins work on the final recommendations, submit either electronic or written comments on the document by December 15, 2015.

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–3474 for ''Draft Recommendations for the Permitted Daily Exposures for Two Solvents, Triethylamine and Methylisobutylketone, According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; International Conference on Harmonisation; Availability.'' 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.

Submit written requests for single copies of the draft recommendations to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft recommendations may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendations.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Timothy J. McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993–0002, 240–402–0477.

Regarding the ICH: Michelle Limoli, CBER International Programs, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7212, Silver Spring, MD 20993–0002, 301–796–8377.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: Europe, Japan, and North America. The eight ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; and Swissmedic. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization.

In the **Federal Register** of December 24, 1997 (62 FR 67377), FDA published the ICH guidance for industry entitled ''Q3C Impurities: Residual Solvents.'' The guidance makes recommendations as to what amounts of residual solvents are considered to be toxicologically acceptable for some residual solvents. Upon issuance in 1997, the text and appendix 1 of the guidance contained several tables and a list of solvents categorizing residual solvents by toxicity, classes 1 through 3, with class 1 being the most toxic. The ICH Quality Expert Working Group (EWG) agreed that the PDE could be modified if reliable and more relevant toxicity data were brought to the attention of the group and the modified PDE could result in a revision of the tables and list.

In 1999, ICH instituted a Q3C maintenance agreement and formed a maintenance EWG (Q3C EWG). The agreement provided for the revisitation of solvent PDEs and allowed for minor changes to the tables and list that include the existing PDEs. The agreement also provided that new solvents and PDEs could be added to the tables and list based on adequate toxicity data. In the **Federal Register** of February 12, 2002 (67 FR 6542), FDA briefly described the process for proposing future revisions to the PDE. In the same notice, the Agency announced its decision to delink the tables and list from the Q3C guidance and create a stand-alone document entitled ''Q3C: Tables and List'' to facilitate making changes recommended by ICH.

In June 2015, the ICH Steering Committee agreed that draft recommendations for a new PDE for the residual solvent triethylamine and a revised PDE for the residual solvent methylisobutylketone should be made available for public comment. The draft recommendations are the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft recommendations provide guidance on the new PDE for the solvent trimethylamine and the revised PDE for the solvent methylisobutylketone. In addition, the data used to derive the PDEs are summarized. The document is intended to recommend acceptable amounts for the listed residual solvents in pharmaceuticals for the safety of the patient.

The draft recommendations are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft recommendations for the solvents trimethylamine and methylisobutylketone, when finalized, will represent the current thinking of FDA on this topic. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.regulations.gov, http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm,* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.*

Dated: October 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–26361 Filed 10–15–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3403]

Clarifying Current Roles and Responsibilities Described in the Coordinated Framework for the Regulation of Biotechnology and Developing a Long-Term Strategy for the Regulation of the Products of Biotechnology; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: Under the auspices of the National Science and Technology Council, the Food and Drug Administration (FDA or the Agency), along with the Office of Science and Technology Policy (OSTP), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA), is announcing a public meeting, to be held on October 30, 2015, to discuss the memorandum entitled, ''Modernizing the Regulatory System for Biotechnology Products,'' issued by the Executive Office of the President (EOP) in July 2015. The purpose of the meeting is to inform the public about the activities described in the July 2015 memorandum; invite oral comments from interested parties; and provide information about how to submit written comments, data, or other information to the docket.

DATES: See section II, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document for the date and time of the public meeting, closing dates for advance registration, and information on deadlines for submitting either electronic or written comments to FDA's Division of Dockets Management. Comments may be submitted in writing until November 13, 2015.

ADDRESSES: See section II, ''How to Participate in the Public Meeting'' in the **SUPPLEMENTARY INFORMATION** section of this document.