

Silver Spring, MD 20993-0002, 301-796-9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2012-3548, appearing on page 8880, in the **Federal Register** of Wednesday, February 15, 2012, the following correction is made:

On page 8880, in the second column, in the Docket No. heading, “[Docket No. FDA-2012-N-1029]” is corrected to read “[Docket No. FDA-2012-N-0129]”.

Dated: February 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4168 Filed 2-22-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0674]

Draft Guidance for Industry: Food and Drug Administration Records Access Authority Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act.” This draft guidance provides updated information pertaining to FDA’s authority to access and copy records relating to food. It is a revision of FDA’s November 2005 guidance entitled “Guidance for Industry and FDA Staff: Guidance for Records Access Authority Provided in Title III, Subtitle A, of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Guidance.”

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 23, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Outreach and Information Center (HFS-009), Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY**

INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

William A. Correll, Jr., Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1611.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act.” The draft guidance is intended for persons who manufacture, process, pack, hold, or import human or animal foods intended for distribution to consumers, institutions, or food processors. This draft guidance provides updated information pertaining to FDA’s authority to access and copy records relating to food under sections 414(a) and 704(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350c(a) and 21 U.S.C. 374(a)(1)(B), respectively), as amended by section 101 of the FDA Food Safety and Modernization Act (FSMA) (Pub. L. 111-353) of January 4, 2011.

Section 414 was originally added to the FD&C Act by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). FSMA, signed into law on January 4, 2011, expanded FDA’s access to records under section 414. Prior to the passage of FSMA, section 414(a) of the FD&C Act provided the Secretary (by delegation FDA) with authority to access records relating to food that was reasonably believed to be adulterated and to present a threat of serious adverse health consequences or death to humans or animals. Now under section 414(a)(1), as amended by FSMA, FDA’s records access extends beyond records relating to the specific suspect article of food to records relating to any other article of food that FDA reasonably believes is likely to be affected in a similar manner. In addition, under section 414(a)(2), FDA can access records if it believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that FDA reasonably believes is likely to be

affected in a similar manner, will cause serious adverse health consequences or death to humans or animals. Furthermore, FSMA revised section 704(a)(1)(B), which pertains to factory inspections, to refer to the amended version of section 414(a).

This updated draft guidance is intended to provide individuals in the human and animal food industries with an overview of FDA’s authority to access and copy records. It provides practical information by answering common questions that cover a range of topics, including when FDA has the authority to access and copy records, the circumstances under which FDA is likely to request records, the types of records FDA may request and copy, and the consequences of refusing to provide records access. The Agency has adopted good guidance practices (GGPs) that set forth the Agency’s policies and procedures for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is being issued as level 1 guidance consistent with GGPs.

The draft guidance, when finalized, will represent the Agency’s current thinking on its authority to access and copy records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to information collection provisions 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 conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Always access an FDA guidance document by using the Web sites listed previously to find the most current version of the guidance.

Dated: February 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-4166 Filed 2-22-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0327]

International Conference on Harmonisation; Final Recommendation for the Revision of the Permitted Daily Exposure for the Solvent Cumene According to the Maintenance Procedures for the Guidance Q3C Impurities: Residual Solvents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final recommendation for the revision of the permitted daily exposure (PDE) for the solvent cumene according to the maintenance procedures for the guidance for industry entitled "Q3C Impurities: Residual Solvents." The recommendation was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

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

ADDRESSES: Submit written requests for single copies of the recommendation to the Division of Drug Information (HFD-

240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft recommendation may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft recommendation.

Submit electronic comments on the recommendation to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding the Q3C Guidance

David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6488, Silver Spring, MD 20993, 301-796-0175.

Regarding the ICH

Michelle Limoli, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3506, Silver Spring, MD 20993-0002, 301-796-4600.

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: The European Union, Japan, and the United States. The six 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; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. 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, Health Canada, and the European Free Trade Area.

In 1999, ICH instituted a Q3C maintenance agreement and formed a maintenance Expert Working Group (Q3C EWG). The agreement provided for the reconsideration 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 PDEs. 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.

II. Revised PDE for Cumene

In the **Federal Register** of July 20, 2010 (75 FR 42098), FDA published a notice announcing the availability of a draft recommendation for the revision of the PDE for cumene according to the ICH maintenance procedures. The notice gave interested persons an opportunity to submit comments by September 20, 2010.

After consideration of the comments received and revisions to the guidance, a final draft of the recommendation was submitted to the ICH Steering Committee and endorsed by the three participating regulatory Agencies in February 2011.

The final recommendation addresses the safety classification of cumene. When the Q3C guidance was published in 1997 (62 FR 67377, December 24, 1997), cumene was listed as a class 3