

ESTIMATES OF HOUR BURDEN—Continued

Program	Estimated number of respondents	Estimated number of responses annually per respondent	Average burden hours per response	Estimated total annual burden hours
Recommendations for All Programs .....	35,705	1	0.25	8,926.3
Supplemental Documents for Application .....	14,540	1	0.75	10,905.0
Feedback Questions .....	53,095	1	0.25	13,273.8
Totals .....	120,730			46,147.5

**Request for Comments**

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia Wagner, Director of Admissions & Registrar, Office of Intramural Training & Education, National Institutes of Health, 2 Center Drive, Building 2/Room 2E06, Bethesda, Maryland 20892-0234, or call 240-476-3619 or e-mail your request, including your address to: [wagnerpa@od.nih.gov](mailto:wagnerpa@od.nih.gov).

**DATES: Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Date: July 15, 2010.

**Michael M. Gottesman,**

*Deputy Director for Intramural Research, National Institutes of Health.*

[FR Doc. 2010-17669 Filed 7-19-10; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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

**International Conference on Harmonisation; Draft 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 draft 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 draft recommendation was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

**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 recommendation before it begins work on the final recommendation, submit either electronic or written comments on the document by September 20, 2010.

**ADDRESSES:** Submit written requests for single copies of the draft 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, suite 200N,

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 draft 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 guidance:* David Jacobson-Kram, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-0175.

*Regarding the ICH:* Michelle Limoli, Office of International Programs (HFG-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4480.

**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 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 safe in pharmaceuticals. The guidance recommends use of less toxic solvents and describes levels 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.

## II. Draft Recommendation to Revise the PDE for Cumene

In March 2010, the ICH Steering Committee agreed that a draft recommendation to revise the PDE for the solvent cumene should be made available for public comment. The draft recommendation is the product of the Q3C EWG of the ICH. Comments about this draft will be considered by FDA and the Q3C EWG.

The draft recommendation addresses the safety classification of cumene. When the Q3C guidance was published in 1997, cumene was listed as a class 3 solvent (i.e., a solvent with low toxicity). The Q3C EWG has reviewed new toxicity data derived from a carcinogenicity study performed by the National Toxicology Program. The new data suggest a positive systemic carcinogenic effect, and this observation raises the toxicity associated with this solvent. In March 2010, the ICH Steering Committee was briefed on the results of the Q3C EWG's analysis. The recommendation was to move cumene from class 3 into class 2. The analysis and draft recommendation are available for review on the Internet (see section IV of this document).

This draft recommendation is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft recommendation for the solvent cumene, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

## 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. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. The draft recommendation and 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 to Documents and the Maintenance Procedures

Persons with access to the Internet may obtain the Q3C guidance documents at <http://www.regulations.gov>, <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>. Information on the Q3C maintenance process as well as proposals, data analysis, and draft and final recommendations for revisions to the tables and list are available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm125820.htm>.

Dated: July 9, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-17618 Filed 7-19-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel Assays of Biological Specimens for Division of Epidemiology, Statistical and Prevention Research.

*Date:* August 10, 2010.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852. (Telephone Conference Call)

*Contact Person:* Sathasiva B. Kandasamy, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892-9304. 301-435-6680.

*skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research;