

solvent (i.e., a solvent with low toxicity). The Q3C EWG 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. The final recommendation is that cumene be placed into class 2. A PDE of 0.7 milligrams per day and a concentration limit of 70 parts per million are being declared for this solvent. The analysis and recommendation are available for review on the Internet (see section V of this document on electronic access). The final recommendation is also available from the Division of Drug Information (see **ADDRESSES**). The Agency will revise the tables in the guidance "Q3C—Tables and List" to reflect the ICH final recommendation for cumene.

The final recommendation for the solvent cumene is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised PDE for the solvent cumene contained in the revised guidance "Q3C—Tables and List" represents 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. Identify comments with the docket number found in brackets in the heading of this document. The 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

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: February 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Request for Nominations for Voting Members on a Public Advisory Committee; Risk Communication Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for members to serve on the Risk Communication Advisory Committee, Office of Planning, Office of Policy and Planning, Office of the Commissioner.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Nominations received on or before April 23, 2012 will be given first consideration for membership on the Risk Communication Advisory Committee. Nominations received after April 23, 2012 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically to cv@oc.fda.gov or by mail to the Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is: Lee L. Zwanziger, Risk Communication Staff, Office of Planning, Office of Policy and Planning, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-9151, Fax: 301-847-8611, RCAC@FDA.HHS.GOV.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: <http://www.fda.gov/AdvisoryCommittees/default.htm>.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting members on the Risk Communication Advisory Committee.

I. General Description of the Committee Duties

The Risk Communication Advisory Committee advises the Commissioner of Food and Drugs or designee on methods to effectively communicate risks associated with products regulated by the Food and Drug Administration and in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The Committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

II. Criteria for Voting Members

The Committee consists of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in fields such as social marketing, health literacy, and other relevant areas. Members will include experts on risk communication, experts on emerging postmarket drug risks and individuals knowledgeable about and experienced in the work of patient, consumer, and health professional organizations. Almost all non-Federal members of this committee serve as Special Government Employees. Some members will be selected to provide experiential insight on the communication needs of the various groups who use FDA-regulated products. The latter may include patients and patients' family members, health professionals, communicators in health, medicine and science, and persons affiliated with consumer, specific disease, or patient safety advocacy groups. Members will be invited to serve for terms of up to 4 years.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 16, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Dates and Times: March 8, 2012, 9 a.m. to 5 p.m. EST. March 9, 2012, 9 a.m. to 12:30 p.m. EST.

Place: Parklawn Building (and via audio conference call), Conference Room 10-65, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, March 8, from 9 a.m. to 5 p.m. (EST) and on Friday, March 9, from 9 a.m. to 12:30 p.m. (EST). The public can join the meeting via audio conference call by dialing 1-800-369-3104 (on March 8 & 9) and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the March meeting will include, but are not limited to: Updates from the Division of

Vaccine Injury Compensation (DVIC), the Department of Justice, the National Vaccine Program Office, the Immunization Safety Office (Centers for Disease Control and Prevention), the National Institute of Allergy and Infectious Diseases (National Institutes of Health), and the Center for Biologics, Evaluation, and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (<http://www.hrsa.gov/vaccinecompensation/accv.htm>) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in attending the meeting in person or providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by email, mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring additional information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-6593; email: aherzog@hrsa.gov.

Dated: February 15, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Opinions and Perspectives About the Current Blood Donation Policy for Men Who Have Sex With Men

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Opinions and Perspectives about the Current Blood Donation Policy for Men Who Have Sex with Men. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The current policy for blood donation in the U.S. with respect to men who have sex with men (MSM) is that any man who discloses having had sex with another man since 1977 is deferred indefinitely from donating. However, data from donors who have tested disease marker positive and were interviewed regarding potential risk factors suggest that some individuals continue to donate blood without disclosing MSM activity in contravention of the policy. In the 1980s there were surveillance studies of risk factors among donors who were determined to be HIV positive in pre-donation testing; Results indicated MSM behavior to be a risk factor for 56% of male donors. In addition, as part of the Retrovirus Epidemiology Donor Study (REDS), when anonymously surveyed by paper and pencil mailed surveys, 1.2% of male blood donors reported MSM behavior.

In a 2007 study conducted in Sweden, 19% of 334 MSM who responded to a survey that was included in a monthly publication targeted to the Lesbian, Gay, Bisexual and Transgender (LGBT) community reported donating blood at least one-time since 1985. The authors suggested that MSM donors may be motivated by perceived discrimination, particularly younger MSM.

Recent publications from the United Kingdom have reported what are likely the only population-based assessment of non-compliance with a similar restriction on blood donation for the MSM population as in the U.S.; this