

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Revised Guidance on Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients

In the **Federal Register** of August 17, 2010 (75 FR 50771), FDA published a notice of availability for a draft revised guidance entitled "Residual Solvents in New Veterinary Medicinal Products, Active Substances and Excipients (Revision) VICH GL18(R)" giving interested persons until October 18, 2010, to comment on the draft revised guidance. This draft incorporated a lower permissible daily exposure limit for N-Methylpyrrolidone, which is still being kept in Class 2, and placed tetrahydrofuran into Class 2 from Class 3. Based on comments received from the draft revised guidance, additional information was added in section 3.2 of this guidance to include reference to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use guideline entitled "Impurities: Guideline for Residual Solvents (Q3C(R4))." The revised guidance announced in this notice finalizes the draft revised guidance announced on August 17, 2010. The revised guidance is a product of the Quality Expert Working Group of the VICH.

III. Paperwork Reduction Act of 1995

This revised 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 this document have been approved under OMB control number 0910–0032.

IV. Significance of Guidance

This revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline". In addition, guidance documents must not include mandatory language such as "shall", "must", "require", or "requirement", unless FDA is using these words to describe a statutory or regulatory requirement.

The revised VICH guidance (GFI #100) is consistent with the Agency's current thinking on this topic. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long

as it satisfies the requirements of applicable statutes and regulations.

V. Comments

Interested persons may, at any time, submit either electronic or written comments regarding this revised guidance document to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: October 27, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–28371 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Interagency Autism Coordinating Committee; Call for Nominations

In accordance with Public Law 112–32, The Combating Autism Reauthorization Act the Department of Health and Human Services has been authorized to continue to support the Interagency Autism Coordinating Committee (IACC) until September 30, 2014 and is seeking nominations for public membership on this committee. The Secretary of the Department of Health and Human Services, who will make the final selections and appointments of public members, has directed the Office of Autism Research Coordination (OARC) to assist the Department in conducting an open and transparent nomination process. Nominations of new public members are encouraged, but current members may also be re-nominated to continue to serve. Self-nominations and nominations of other individuals are both permitted. Only one nomination per individual is required. Multiple nominations for the same individual will not increase likelihood of selection. The Secretary may select public members from the pool of submitted

nominations and other sources as needed to meet statutory requirements and to form a balanced committee that represents the diversity within the community (details below). Those eligible for nomination include leaders or representatives of major autism spectrum disorder (ASD) research, advocacy and service organizations, parents or guardians of individuals with ASD, individuals on the autism spectrum, providers, educators, researchers and other individuals with professional or personal experience with ASD. In accordance with White House Office of Management and Budget guidelines (FR Doc. 2011–25736), federally-registered lobbyists are not eligible. As specified in Public Law 109–416, which has been extended by Public Law 112–32, the Committee will carry out the following responsibilities: (a) Develop a summary of advances in autism spectrum disorder research supported or conducted by the Federal agencies relevant to causes, prevention, treatment, early screening, diagnosis or rule out, intervention, and access to services and supports for individuals with autism spectrum disorder; (b) monitor Federal activities with respect to autism spectrum disorder; (c) make recommendations to the Secretary regarding any appropriate changes to such activities, including recommendations to the Director of NIH with respect to the strategic plan; (d) make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder; (e) develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements.

In accordance with Public Law 109–416, which has been extended by Public Law 112–32, “Not fewer than 6 members of the Committee, or 1/3 of the total membership of the Committee, whichever is greater, shall be composed of non-Federal public members appointed by the Secretary, of which— (a) at least one such member shall be an individual with a diagnosis of autism spectrum disorder; (b) at least one such member shall be a parent or legal guardian of an individual with an autism spectrum disorder; and (c) at least one such member shall be a representative of leading research, advocacy, and service organizations for individuals with autism spectrum disorder.”

Public members of the Committee shall serve for a term of 4 years, and may be reappointed for one or more additional 4 year terms. Any member appointed to fill a vacancy for an

unexpired term shall be appointed for the remainder of such term. A member may serve after the expiration of the member’s term until a successor has taken office. Public members will serve as Special Government Employees. The Committee shall meet at the call of the chairperson or upon the request of the Secretary. The Committee shall meet not fewer than 2 times each year.

In 2008–2011, the Committee held an average of 15 meetings, workshops and phone conferences per year. Travel expenses are provided for Committee members to facilitate attendance at in-person meetings.

The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee’s function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS Federal advisory committees and, therefore, the Department encourages nominations of qualified candidates from these groups. The Department also encourages geographic diversity in the composition of the Committee. Appointment to this Committee shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status. Requests for reasonable accommodation to enable participation on the Committee should be indicated in the nomination submission. Nominations are due by COB November 30, 2011 and may be sent to Dr. Susan Daniels, Acting Director, Office of Autism Research Coordination/NIMH/NIH, 6001 Executive Boulevard, Room 8185, Bethesda MD 20892–2190 by standard or express mail, or via email to IACCPublicInquiries@mail.nih.gov. Nominations should include a cover letter of no longer than 3 pages describing the candidate’s interest in seeking appointment to the IACC, including relevant personal and professional experience with ASD, as well as contact information and a current curriculum vitae or resume. Please do not include additional materials unless requested. More information about the IACC is available at <http://www.iacc.hhs.gov>.

Dated: October 27, 2011.

Susan A. Daniels,

Acting Director, Office of Autism Research Coordination, National Institute of Mental Health.

[FR Doc. 2011–28375 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Pilot and Feasibility Clinical Research Studies in Digestive, Diseases and Nutrition.

Date: November 14, 2011.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Peter J Perrin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, (301) 435–0682, perrinp@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 27, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–28370 Filed 11–1–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is