

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Process Validation: General Principles and Practices." This guidance outlines the general principles and approaches that FDA considers to be appropriate elements of process validation for the manufacture of human and animal drug and biological products, including active pharmaceutical ingredients (API or drug substance). This guidance incorporates principles and approaches that all manufacturers can use in validating a manufacturing process.

In the **Federal Register** of May 11, 1987 (52 FR 17638), FDA issued a notice announcing the availability of a guidance entitled "Guideline on General Principles of Process Validation" (the 1987 guidance). Since then, we have obtained additional experience through our regulatory oversight that allows us to update our recommendations to industry on this topic. The draft guidance conveys FDA's current thinking on process validation and is consistent with basic principles first introduced in the 1987 guidance. The draft guidance also provides recommendations that reflect some of the goals of FDA's initiative entitled "Pharmaceutical CGMPs for the 21st Century—A Risk-Based Approach," particularly with regard to the use of technological advances in pharmaceutical manufacturing, as well as implementation of modern risk management and quality system tools and concepts. When finalized, this guidance will replace the 1987 guidance.

FDA's current good manufacturing practice (CGMP) regulations for validating pharmaceutical (drug) manufacturing require that drug products be produced with a high degree of assurance that they meet all the attributes they are intended to possess (21 CFR 211.100(a) and 211.110(a)). Effective process validation contributes significantly to the assurance of drug quality. FDA has the authority and responsibility to inspect and evaluate process validation performed by manufacturers.

This guidance aligns process validation activities with the product lifecycle concept and with existing FDA guidance, including International Conference on Harmonisation (ICH) guidance documents, "Q8 Pharmaceutical Development," "Q9 Quality Risk Management," and when it is finalized, "Q10 Pharmaceutical Quality System" (a notice of availability for the May 2007 ICH Q10 draft guidance published in the **Federal**

Register on July 13, 2007 (72 FR 38604)) (the guidances are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>). The lifecycle concept links product and process development, qualification of the commercial manufacturing process, and maintenance of the process in a state of control during routine commercial production. This guidance promotes modern manufacturing principles, process improvement innovation, and sound science.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the general principles and practices of process validation. 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.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that 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 collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR part 211, and is approved under OMB Control Number 0910–0139.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://>

www.fda.gov/cder/guidance/index.htm, <http://www.fda.gov/cber/guidelines.htm>, <http://www.fda.gov/cvm/guidance/published.htm>, or <http://www.regulations.gov>.

Dated: November 10, 2008.

Jeffery Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27321 Filed 11–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 9, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Ronald P. Jean, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3676, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512521. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss, make recommendations and vote on a premarket approval application for

Synvisc-One, sponsored by Genzyme Corp. This device is indicated for the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 25, 2008. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the deliberations. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 19, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 20, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams, Conference Management Staff, 240-276-8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee

meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 10, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-27255 Filed 11-18-08; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Council of Councils, November 20, 2008, 8:30 a.m. to November 21, 2008, 12:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 6, 2008, 73 FR 66052.

The closed session of the meeting has been cancelled. The meeting will be held on November 20-21, 2008. The meeting is open to the public.

Dated: November 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-27264 Filed 11-17-08; 8:45 am]

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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. Appendix 2), 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: National Institute of Child Health and Human Development Special Emphasis Panel Evaluation of Fetal Structural Malformations.

Date: November 17, 2008.

Time: 3 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Bldg. Rm. 5B01, Rockville, MD 20852, (301) 435-6889, bhatnagg@mail.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. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: November 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-27253 Filed 11-17-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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: Heart, Lung, and Blood Initial Review Group, Heart, Lung, and Blood Program Project Review Committee.

Date: December 5, 2008.

Time: 8 a.m. to 2 p.m.