ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira__submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—(OMB Control Number 0910–0275—Extension)

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

In the **Federal Register** of July 18, 2008 (73 FR 41360), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: November 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27258 Filed 11–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0559]

Draft Guidance for Industry on Process Validation: General Principles and Practices; 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 ''Process Validation: General Principles and Practices.'' FDA is revising its guidance for industry entitled ''Guideline on General Principles of Process Validation,'' which issued in May 1987 (the 1987 guidance). The revised draft guidance promotes a ''lifecycle'' approach to process validation that includes scientifically sound design practices, robust qualification, and process verification. When finalized, this draft guidance will replace the 1987 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 comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 20, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Brian Hasselbalch, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279;

Grace McNally, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993–0002, 301–301–796–3286;

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION:

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]

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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