is taking this action in response to a request for an extension of the comment period, due to the holiday season, to allow interested persons sufficient time to review this draft guidance and submit comments.

DATES: Submit written or electronic comments by March 16, 2009.

ADDRESSES: Submit written comments 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*.

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; or

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, 301–796–3286; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 5515 Security Lane, rm. 7302, Rockville, MD 20852, 301–435–5681; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8268.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is extending the comment period on a draft guidance for industry entitled ''Process Validation: General Principles and Practices.''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.

FDA issued the draft guidance on November 18, 2008. The initial comment period closes on January 20, 2009. In response to a request for an extension, due to the holiday season, to allow interested persons sufficient time to review this draft guidance and submit comments, FDA has decided to reopen the comment period until March 16, 2009.

II. 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.

III. 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: February 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3090 Filed 2–12–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: 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: Cardiovascular and Renal Drugs 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 March 19, 2009, from 8 a.m. to 5 p.m.

Location: Marriott Conference Centers, UMUC Inn and Conference Center by Marriott, 3501 University Blvd., East, Adelphi, MD. The hotel telephone number is 301–985–7385.

Contact Person: Elaine Ferguson, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *elaine.ferguson@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512533. 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 new drug application (NDA) 22–406, rivaroxaban oral tablets (10 milligrams) Johnson & Johnson Pharmaceutical Research & Development, L.L.C., for the proposed indication for use in prophylaxis of deep vein thrombosis and pulmonary embolism in patients undergoing hip replacement surgery or knee replacement surgery.

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 2009 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 March 5, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. 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 February 25, 2009. 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 February 26, 2009.

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 Elaine Ferguson 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: February 4, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–3089 Filed 2–12–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Guidance

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Final Agency Guidance and Response to Public Comments.

SUMMARY: HRSA is publishing a final Agency Guidance (''Policy Information Notice'' (PIN) 2009–02), to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project. The PIN, ''Specialty Services and Health Centers'' Scope of Project,'' and the Agency's ''Response to Public Comments'' are available on the Internet at *http://bphc.hrsa.gov.*

DATES: The effective date of this final Agency guidance is December 18, 2008.

Background: The Health Resources and Services Administration administers the Health Center Program, as authorized by section 330 of the Public Health Service (PHS) Act as amended, (42 U.S.C. 254b). Health centers improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. Health center grants support a variety of community-based and patient-directed public and private nonprofit organizations and continue to serve an increasing number of the Nation's underserved. Charges for health care services are set according to income. At the end of the 2007 calendar year, there were more than 1,000 federally-funded health centers with more than 7,000 primary health care delivery sites located in urban and rural underserved areas throughout the U.S. and its territories. In 2007, over 16 million medically underserved and uninsured patients received comprehensive, culturally competent, quality primary health care services through the federally-supported Health Center Program.

On August 10, 2007, HRSA made the draft PIN, ''Specialty Services and Health Centers'' Scope of Project,'' available for public comment on HRSA's Web site. HRSA also published a notice in the **Federal Register** of August 29, 2007, requesting comments on this draft PIN.

Sixty-five comments were received from 20 organizations and/or individuals. After review and careful consideration of all comments received, HRSA has amended the PIN to incorporate certain recommendations from the public. The final PIN reflects these changes.

In addition to making the final PIN available on HRSA's Web site, HRSA is also posting the Agency's ''Response to Public Comments'' at *http://bphc.hrsa.gov/policy/pin0902/pin0902comments.htm*. The purpose of that document is to summarize the major comments received and describe the Agency's response, including any corresponding changes made to the PIN. Where comments did not result in a revision to the PIN, explanations are provided. Any interested party that does not have access to HRSA's Web site can contact the HRSA point of contact to request that a hardcopy of the ''Response to Public Comments'' be mailed to their attention.

FOR FURTHER INFORMATION CONTACT: For questions regarding this notice, please contact the Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, at 301–594–4300.

Dated: February 6, 2009.

Elizabeth M. Duke,

Administrator.

[FR Doc. E9–3087 Filed 2–12–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Final Policy Guidance

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final Guidance.

DATES: The effective date of this final Agency guidance is January 5, 2009.

SUMMARY: HRSA has issued Policy Information Notice (PIN) 2009–04, ''Revision to PIN 2003–21: Federally Qualified Health Center (FQHC) Look-Alike Guidelines and Application,'' to announce a technical revision to *PIN 2003–21: FQHC Look-Alike Guidelines and Application*, issued on August 26, 2003. Both PINs are available on HRSA's Web site at *http://bphc.hrsa.gov/policy/#lookalikes.*

Background: HRSA has issued PIN 2009–04, ''Revision to PIN 2003–21: FQHC Look-Alike Guidelines and Application,'' to announce a technical revision to *PIN 2003–21: FQHC Look-Alike Guidelines and Application*, issued on August 26, 2003. PIN 2003–21 conveys eligibility and compliance requirements of the FQHC Look-Alike Program and instructions for submitting an application for FQHC Look-Alike designation, recertification, and change in scope of project. PIN 2009–04 updates the data submission requirements in PIN 2003–21. Applicants and existing FQHC Look-Alikes should refer to both PINs when preparing applications. Both PINs are available on HRSA's Web site at *http://bphc.hrsa.gov/policy/#lookalikes*.

PIN 2009–04 reflects the Office of Management and Budget (OMB) approved extension of information collection (control number 0915–0142) to November 30, 2011. Furthermore, the race and ethnicity data is now collected as two separate data elements in Table 2, Part B, to meet OMB Standards for the Classification of Federal Data on Race and Ethnicity as well as Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (62 FR 36874–36946; 62 FR 58781–9; and OMB Bulletin #00–02). Please note that all information provided regarding race and/or ethnicity will be used only to ensure compliance with statutory and regulatory Governing Board requirements set forth in section 330 of the Public Health Service Act. Data on race and/or ethnicity collected on this form will not be used as a factor in recommending approval for FQHC