Public Scoping Meeting

The public scoping meeting will be held at Van Ness Elementary School, 1150 5th St., SE., Washington, DC on December 3, 2002, from 6 to 8:30 pm. The meeting will be an informal open house, where visitors may come, receive information, discuss the proposal with study team members, give their comments, and leave anytime during the meeting period. GSA will publish notices announcing this meeting approximately two weeks prior to the meeting in the *Washington Post,* the *Washington Times,* and appropriate neighborhood newspapers, and through direct mailing to local and community organizations. GSA will prepare a scoping report, available to the public, that will summarize the comments received and facilitate their incorporation into the EIS process.

Throughout the EIS process, information on the project and its progress may be found on the GSA website: *http://www.gsa.gov/southeastfederalcenter*

Written Comments: Agencies and the public are encouraged to provide written comments on the scoping issues in addition to or in lieu of giving their comments at the public scoping meeting. Written comments regarding the environmental analysis for the development of the SEFC must be postmarked no later than December 17, 2002 and sent to the following address: General Services Administration, Attention: Patricia Daniels, Project Executive, 7th & D Streets, SW., Suite 2002, Washington, DC 20407.

Scoping Meeting Place

The meeting will be held at the following address: Van Ness Elementary School, 1150 5th St., SE., Washington, DC.

Date: December 3, 2002.

Time: 6 pm to 8:30 pm.

FOR FURTHER INFORMATION CONTACT: Patricia Daniels, Project Executive, General Services Administration, National Capital Region, (202) 205–5857. Please also call this number if special assistance is needed to participate in the scoping meeting.

Dated: November 5, 2002.

Donald C. Williams,

Regional Administrator, National Capital Region, General Services Administration.

[FR Doc. 02–28838 Filed 11–12–02; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

White House Initiative on Asian Americans and Pacific Islanders President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to conduct a public meeting during the month of October 2002.

Name: President's Advisory Commission on Asian Americans and Pacific Islanders (Commission).

Date and Time: Friday, November 22, 2002; 10 a.m.–5 p.m. EST.

Location: Key Bridge Marriott, 1401 Lee Highway, Arlington, VA 22209.

The meeting is open to the public.

The President's Advisory Commission on AAPIs will conduct a public meeting on November 22, 2002, from 10 a.m. to 5 p.m. EST inclusive.

Agenda items will include, but may not be limited to: Presentations of preliminary reports by subcommittees of the President's Advisory Commission in the subject areas of health, economic and community development, education and immigration; Commission deliberations of subcommittee reports; administrative tasks; deadlines; upcoming events; and comments from the public.

The purpose of the Commission is to advise and make recommendations to the President on ways to increase opportunities for and improve the quality of life of approximately thirteen million Asian Americans and Pacific Islanders living in the United States and the U.S. associated Pacific Island jurisdictions, especially those who are most underserved.

Requests to address the Commission must be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and make their request to address the Commission through a single representative. The allocation of time for remarks will be adjusted to accommodate the level of expressed interest. Written requests must be faxed to (301) 443–0259.

Anyone who has interest in joining any portion of the meeting or who requires additional information about the Commission should contact: Ms. Betty Lam or Mr. Erik F. Wang, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD, 20857, Telephone (301) 443–2492. Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Wang no later than November 18, 2002.

Dated: November 8, 2002.

Willis Morris,

Senior Advisor to the Deputy Secretary.

[FR Doc. 02–28880 Filed 11–8–02; 11:16 am]

BILLING CODE 4165–15–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0452]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations regarding approval of certain new drug and biological products based on efficacy studies conducted in non-human animals.

DATES: Submit written or electronic comments on the collection of information by January 13, 2003.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible

FDA has amended its new drug and biological product regulations to allow appropriate studies in animals in certain cases to provide substantial evidence of effectiveness of new drug and biological products used to reduce or prevent the toxicity of chemical, biological, radiological, or nuclear substances when adequate and well-controlled efficacy studies in humans cannot be ethically conducted because the studies would involve administering a potentially lethal or permanently disabling toxic substance or organism to healthy human volunteers, and field trials are not feasible before approval. In these circumstances, when it may be impossible to demonstrate effectiveness through adequate and well-controlled studies in humans, FDA is providing that certain new drug and biological products intended to treat or prevent serious or life-threatening conditions could be approved for marketing based on studies in animals, without the traditional efficacy studies in humans. FDA is taking this action because it recognizes the importance of improving medical response capabilities to the use of lethal or permanently disabling chemical, biological, radiological, and nuclear substances in order to protect individuals exposed to these substances.

Respondents to this information collection are business and other for-profit organizations and nonprofit institutions.

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
314.610(b)(2), 314.630, 601.91(b)(2), and 601.93	1	1	1	5	5
314.610(b), 314.640, 601.91(b), and 601.94	1	1	1	240	240
Total					245

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
314.610(b)(2), 314.630, 601.91(b)(2), and 601.93	1	1	1	1	1
314.610(b), and 601.91(b)	1	1	1	1	1
Total					2

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

FDA estimates that only one application of this nature may be submitted every 3 years; however for calculation purposes, FDA is estimating the submission of one application annually. FDA estimates 240 hours for a manufacturer of a new drug or biological product to develop patient labeling and to submit the appropriate information and promotional labeling to FDA. At this time, FDA cannot estimate the number of postmarketing reports for information collection. These reports are required under 21 CFR parts 310, 600, and 314. Any requirements will be reported under the adverse experience reporting (AER) information collection requirements. The estimated hours for postmarketing reports range from 1 to 5 hours based on previous estimates for AER; however, FDA is estimating 5 hours for the purpose of this information collection.

The majority of the burden for developing the patient labeling is included under the reporting requirements; therefore, minimal

burden is calculated for providing the guide to patients. As discussed previously, no burden can be calculated at this time for the number of AER reports that may be submitted after approval of a new drug or biologic. Therefore, the number of records that may be maintained also cannot be determined. Any burdens associated with these requirements will be reported under the AER information collection requirements. The estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

Dated: November 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28854 Filed 11–12–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0355]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Device Recall Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 13, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Medical Device Recall Authority—21 CFR Part 810 (OMB Control Number 0910–0432)—Extension

This collection implements medical device recall authority provisions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810). Section 518(e) of the act gives FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device to immediately cease distribution of such device, to immediately notify health professionals and device-user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

Section 518(e) of the act sets out a three-step procedure for issuance of a mandatory device recall order. First, if there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately: (a) Cease distribution of the device, (b) notify health professionals and device user facilities of the order, and (c) instruct those professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

The respondents to this proposed collection of information are manufacturers, importers, distributors, and retailers of medical devices.

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

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
810.10(d)	2	1	2	8	16
810.11(a)	1	1	1	8	8
810.12(a) through (b)	1	1	1	8	8
810.14	2	1	2	16	32
810.15(a) through (d)	2	1	2	16	32
810.15(e)	10	1	10	1	10
810.16	2	12	24	40	960
810.17	2	1	2	8	16
Total					1,082

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

Explanation of Report Burden Estimate:

The following estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total annual burden is 16 hours.

Section 810.11(a)—Based on its experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately one staff day (8 hours) to prepare this request.