

Part VI is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of the analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark

Secretary.

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GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0228]

Office of Civil Rights; Submission for OMB Review; Nondiscrimination in Federal Financial Assistance Programs

AGENCY: Office of Civil Rights, GSA.

ACTION: Notice of request for comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the General Services Administration will be submitting to the Office of Management and Budget (OMB) a request to review and approve a previously approved information collection requirement regarding nondiscrimination in Federal financial assistance programs. This information is needed to facilitate nondiscrimination in GSA's Federal Financial Assistance Programs, consistent with Federal civil rights laws and regulations that apply to recipients of Federal financial assistance.

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

DATES: Submit comments on or before: November 16, 2009.

FOR FURTHER INFORMATION CONTACT: Sloan Farrell, Compliance Officer, Office of Civil Rights, at telephone (202) 501-4347 or via e-mail to sloan.farrell@gsa.gov.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the Regulatory Secretariat

(MVPR), General Services Administration, 1800 F Street, NW., Room 4041, Washington, DC 20405. Please cite OMB Control No. 3090-0228, Nondiscrimination in Federal Financial Assistance Programs, in all correspondence.

SUPPLEMENTARY INFORMATION:

A. Purpose

The General Services Administration (GSA) has mission responsibilities related to monitoring and enforcing compliance with Federal civil rights laws and regulations that apply to Federal Financial Assistance programs administered by GSA. Specifically, those laws provide that no person on the ground of race, color, national origin, disability, sex or age shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program in connection with which Federal financial assistance is extended under laws administered in whole or in part by GSA. These mission responsibilities generate the requirement to request and obtain certain data from recipients of Federal surplus property for the purpose of determining compliance, such as the number of individuals, based on race and ethnic origin, of the recipient's eligible and actual serviced population; race and national origin of those denied participation in the recipient's program(s); non-English languages encountered by the recipient's program(s) and how the recipient is addressing meaningful access for individuals that are Limited English Proficient; whether there has been complaints or lawsuits filed against the recipient based on prohibited discrimination and whether there has been any findings; and whether the recipient's facilities are accessible to qualified individuals with disabilities.

B. Annual Reporting Burden

Respondents: 200.

Responses per Respondent: 1.

Total Responses: 200.

Hours per Response: 2.

Total Burden Hours: 400.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVPR), 1800 F Street, NW., Room 4041, Washington, DC 20405, telephone (202) 501-4755. Please cite OMB Control No. 3090-0228, Nondiscrimination in Federal Financial Assistance Programs, in all correspondence.

Dated: October 8, 2009.

Casey Coleman,

Chief Information Officer.

[FR Doc. E9-24879 Filed 10-15-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0475]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

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 extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for administrative detention and banned medical devices.

DATES: Submit written or electronic comments on the collection of information by December 15, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (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: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793, Denver.Presley@fda.hhs.gov.

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 extension 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 these topics: (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.

Administrative Detention and Banned Medical Devices (OMB Control Number 0910-0114)—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 334(g)), to detain during established inspections, devices that are believed to be adulterated or misbranded. FDA issued a final rule that published in a March 9, 1979, **Federal Register** (44 FR 13234) on administrative detention procedures, which includes among other things, certain reporting requirements and recordkeeping requirements under § 800.55(g) and (k), (21 CFR 800.55(g) and (k)). Under § 800.55(g), an applicant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permits FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. The final rule for banned devices that published in the May 18, 1979, **Federal Register** (44 FR

29221) contained certain reporting requirements under 21 CFR 895.21(d) and 895.22(a). Section 895.21(d) states that if the Commissioner of Food and Drugs Administration (the Commissioner), decides to initiate a proceeding to make a device, "a banned device," a notice of proposed rulemaking will be published in the **Federal Register** and this document will contain the finding that the device presents a substantial deception or an unreasonable and substantial risk of illness or injury. The document will also contain the reasons why the proceeding was initiated, an evaluation of data and information obtained under other provisions of the act, any consultations with the panel, and a determination as to whether the device could be corrected by labeling, change of labeling, change of advertising, and if that labeling or change of advertising has been made. Under § 895.21(d), any interested person may request an informal hearing and submit written comments. Under § 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
800.55(g)	1	1	1	25	25
895.21(d) and 895.22(a)	26	1	26	16	416
Totals					441

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record-keeping	Total Annual Records	Hours per Recordkeeper	Total Hours
800.55(k)	1	1	1	20	20
Totals					461

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

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will

have varying amounts of data and information that must be maintained. FDA's estimate of the burden under the administrative detention provision is

based on FDA's discussion with one of three firms whose devices had been detained.

Dated: October 8, 2009.

David Horowitz,
Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Evaluation of the NIAID HIV Vaccine Research Education Initiative

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 16, 2009, page 34580 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public

comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Evaluation of the NIAID HIV Vaccine Research Education Initiative. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* To address the need for volunteers in HIV vaccine clinical trials, and enable NIAID to fulfill its Congressional mandate to prevent infectious diseases like HIV/AIDS, NIAID created the NIAID HIV Vaccine Research Education Initiative (NHVREI). The goal of NHVREI is to increase knowledge about and support for HIV vaccine research among U.S. populations most heavily affected by HIV/AIDS—in particular, African Americans, Hispanics/Latinos, men who have sex with men (MSM), women and youth, recognizing the intersection of these groups.

NIAID is planning an evaluation of NHVREI to assess (a) implementation of NHVREI (*i.e.*, process evaluation) and (b) impact (*i.e.*, outcomes evaluation) of NHVREI on awareness of, knowledge about, and support for HIV vaccine research among NHVREI primary audiences (*i.e.*, partner organizations,

key influencers) that work with target populations.

A survey will be conducted with key influencers of the NHVREI target populations to measure their level of awareness, knowledge about, and support for HIV vaccine research. Focus groups will also be conducted with representatives of organizations receiving grants through the NHVREI Local Partnership Program (LPP) and National Partnership Program (NPP), as well as representatives from a broader group of organizations called the NHVREI Network. The purpose of conducting focus groups with LPP, NPP, and NHVREI Network representatives is to obtain data on their experience implementing NHVREI activities. Questions asked during the group discussions will address efforts implementing educational activities and developing materials, community partnerships developed, engagement of key influencers in program activities, and the types of media outreach and capacity building engaged in. *Frequency of Response:* Twice. *Affected Public:* Individuals. *Type of Respondents:* Key influencers of target populations. The annual reporting burden is shown in the table below. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Form name	Estimated number of respondents	No. of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
LPP, NPP, and NHVREI Network Key Influencers	<i>Time 1</i> Focus Groups	78	1	1	78
	Survey	656	1	0.33	216
	Total Time 1	734			294
LPP, NPP, and NHVREI Network Key Influencers	<i>Time 2</i> Focus Groups	78	1	1	78
	Survey	590	1	0.33	195
	Total Time 2	668			273
	Total Time 1 & Time 2	1,402			567

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden

of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: Desk Officer for NIH. To request more

information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Katharine Kripke, Assistant Director, Vaccine Research Program, Division of AIDS, NIAID, NIH, 6700B Rockledge Dr., Bethesda, MD 20892-7628, or call non-toll-free number 301-402-0846, or E-mail your request, including your address to *NIAIDSurvey@nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.