

Dated: August 3, 2009.

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Acting Reports Clearance Officer, Centers for Disease Control and Prevention.
 [FR Doc. E9-20967 Filed 8-28-09; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0565]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, *Elizabeth.Berbakos@fda.hhs.gov*, 301-796-3792.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 28, 2009 (74 FR 19225), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0396. The approval expires on August 31, 2012. A copy of the supporting statement for this information collection is available on

the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: August 21, 2009.

David Horowitz,
Assistant Commissioner for Policy.
 [FR Doc. E9-20895 Filed 8-28-09; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of the NIAID HIV Vaccine Research Education Initiative

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: *Title:* Evaluation of the NIAID HIV Vaccine Research Education Initiative, Highly Impacted Population Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* Developing measures that protect against HIV infection is one of NIAID's highest priorities. Methods in development for the prevention of HIV infection include: HIV vaccines, microbicides, and pre-exposure prophylaxis (PrEP). Given the daunting complexity of the HIV virus, developing these methods will ultimately require tens of thousands of volunteers to participate in HIV prevention clinical trials. In the U.S., minority participation in clinical trials of HIV prevention technologies is essential; nearly two-thirds of people diagnosed with HIV in the United States are African American or Hispanic/Latino. Historically, recruitment of racial/ethnic populations has been a critical challenge for medical researchers, and initiatives to increase recruitment of these groups into cancer and chronic disease trials have only been partially successful.

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.

A critical component of NHVREI is outreach to members of these specific highly impacted populations. With the assistance of funded community-based and national organizations, NHVREI is designing, developing, and disseminating HIV vaccine research-related messages to NHVREI target audiences. These messages are delivered through print (e.g., brochures, posters, fact sheets, information kits), radio, TV, and Internet resources. Print materials are distributed through various NHVREI program activities (e.g., trainings, conferences, symposia) and other NIAID-funded partners, governmental and non-governmental organizations.

NIAID is conducting an evaluation of the NHVREI program in order to assess its impact and generate key findings applicable toward the design of future educational initiatives. Part of the evaluation includes a population survey to guide future NHVREI activities.

With this document, NIAID requests clearance for the third part of the evaluation, a survey of the general population and members of the U.S. populations most heavily impacted by HIV/AIDS. The survey will be conducted once in 2010. The total number of respondent burden hours will not exceed 1167 annually. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* General U.S. population with oversampling of subpopulations highly impacted by HIV. 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.

	Total No. of respondents	Hours per response	Total hours
Highly Impacted Population Surveys	3,500	0.33333	1,167

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited

on one or more of the following points: (1) 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;