TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS—Continued

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (min/hr)	Annual burden hours
Board Members	Pediatric CIRB Reviewer Findings—Initial Review of Cooperative Group Protocol (Attachment 6B).	12	1	4 hours	48
Board Members	Adult CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6C).	25	1	1 hour	25
Board Members	Pediatric CIRB Reviewer Findings Cooperative Group Response to CIRB Review (Attachment 6D).	70	1	1 hour	70
Board Members	Adult CIRB Reviewer Findings Amendment Cooperative Group Protocol (Attachment 6E).	130	1	1.5 hours	195
Board Members	Pediatric CIRB Reviewer Findings Amendment to Cooperative Group Protocol (Attachment 6F).	50	1	1.5 hours	75
Board Members	Adult CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6G).	150	1	.5 hour	75
Board Members	Pediatric CIRB Reviewer Findings Continuing Review of Cooperative Group Protocol (Attachment 6H).	110	1	.5 hour	55
Board Members	CIRB Reviewer Form (Attachment 6I)	20	1	2 hours	40
Board Members	CIRB Statistical Reviewer Form (Attachment 6J).	20	1	2 hours	40
Board Members	CIRB SAE Reviewer Worksheet (Attachment 6K).	10	15	30/60 (.5 hour)	75
Total	.....	4,904	.....	.....	2,209

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 Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Jeanne Adler, Division of Cancer Treatment and Diagnosis or call non-toll-free number 301–594–0083 or e-mail your request, including your address to: *adlerj@mail.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.

Dated: November 10, 2010.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010–28883 Filed 11–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Pretesting of NIAID's Biomedical HIV Prevention Research Communication Messages

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: Pretesting of NIAID's Biomedical HIV Prevention Research Communication Messages. *Type of Information Collection Request:* Revision of a previously approved collection. *Need and Use of Information Collection:* This is a request for clearance to pretest messages, materials and program activities about biomedical HIV prevention research. The primary objectives of the pretests are to (1) Assess audience knowledge, attitudes, behaviors and other characteristics for the planning/development of health messages, education products, communication strategies, and public information programs; and (2) pretest these health messages, products, strategies, and program components while they are in developmental form to assess audience comprehension, reactions, and perceptions. The information obtained from audience research and pretesting results in more effective messages, materials, and programmatic strategies. By maximizing the effectiveness of these messages and strategies for reaching targeted audiences, the frequency with which publications, products, and programs

need to be modified is reduced. *Frequency of Response:* On occasion. *Affected Public:* Individuals. *Type of Respondents:* Adults at risk for HIV/AIDS; representatives of organizations disseminating HIV-related messages or materials. 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	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
General public	2,988	1	.40	1,195.2
Community-Based Organization Managers	749	1–3	.31	232.19
Healthcare Providers	107	1	.32	34.24
Total	3,844			1,461.63

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.

FOR FURTHER INFORMATION: 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 *kripkek@niaid.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: November 10, 2010.

John J. McGowan,

Deputy Director for Science Management NIAID.

[FR Doc. 2010–28980 Filed 11–16–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0515]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Non-Powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)." This guidance document describes a means by which non-powered suction apparatus devices intended for NPWT may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify non-powered suction apparatus devices intended for NPWT into class II (special controls). This guidance document is immediately in effect as the special control for non-powered suction apparatus devices intended for NPWT, but it remains subject to comment in accordance with the Agency's good guidance practices (GGPs).

DATES: Submit either electronic or written comments on the guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Non-powered Suction Apparatus Device Intended for Negative Pressure Wound Therapy (NPWT)" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4617, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jiyoung M. Dang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3615, Silver Spring, MD 20993, 301–796–5650.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying non-powered suction apparatus devices intended for negative pressure wound therapy into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for non-powered suction apparatus devices intended for negative pressure wound therapy device. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act, request that FDA classify the device under the criteria set forth in section