(Response 11) CSPI suggested extensive changes to the Nutrition Facts label that affect many parts of the label. In this research, the Agency is focused on how consumers use labels for products that are customarily consumed at one eating occasion but may contain more than one serving per container as well as on how consumers react to different ways that calorie information is declared on the label. FDA believes these changes have the potential to be among the most useful changes to help consumers make informed choices. Therefore, FDA identified and chose the proposed formats, such as dual column formats and prominence of calorie formats, for this study. The variety of different experimental conditions for just these changes requires a very large number of respondents. It is not feasible to test the additional extensive changes such as those suggested by CSPI in this study because the number of respondents needed would become unmanageable.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Portion of study	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Cognitive interview screener	96	1	96	0.083	8
Cognitive interview	12	1	12	1	12
Pretest invitation	1,000	1	1,000	0.033	33
Pretest	150	1	150	0.25	38
Experiment invitation	50,000	1	50,000	0.033	1,650
Experiment	10,000	1	10,000	0.25	2,500
Total					4,241

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

In the 60-day notice that published in the **Federal Register** of November 18, 2009, we estimated a total burden of 1,595 hours for the study. In this document, table 1 has been modified to reflect our re-evaluation of the original study design. The new total estimated burden is 4,241 hours.

To help design and refine the questionnaire to be used for the experimental study, we plan to conduct cognitive interviews by screening 96 adult consumers in order to obtain 12 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hours) and each cognitive interview is expected to take 1 hour. The total for cognitive interview activities is 20 hours (8 hours + 12 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 150 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 71 hours (33 hours + 38 hours). For the experiment, we estimate that 50,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10,000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the experiment activities is 4,150 hours (1,650 hours + 2,500 hours). Thus, the total estimated burden is 4,241 hours. FDA's burden estimate is based on prior experience with research that is similar to this proposed study.

II. References

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4. Lando A. and J. Labiner-Wolfe, "Helping Consumers to Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," *Journal of Nutrition Education and Behavior* 39: 157–163, 2007.
5. U.S. Food and Drug Administration, Calories Count: Report of the Working Group on Obesity, 2004, (*http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm*).
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Dated: November 10, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28966 Filed 11–16–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; NIH NCI Central Institutional Review Board (CIRB) Initiative (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), 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 August 16, 2010 (75 FR 49938) and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow 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: NIH NCI Central Institutional Review Board (CIRB). *Type of Information Collection Request:* Existing Collection in Use Without an OMB Number. *Need and Use of Information Collection:* The CIRB was created to reduce the administrative burden on local IRBs and investigators while protecting human research participants. To accomplish this, the CIRB uses several information collection tools to ensure that CIRB operations occur with high level of reviewer and board member satisfaction and is absent of conflicts of interest with the protocols under review. Tools utilized to accomplish this include the new member packets which are completed once a new member joins the CIRB to provide background information on workflow and processes of CIRB operations as well as a non-disclosure agreement. A conflict of interest form is completed occasionally or each time the reviewer is requested to serve as a reviewer for a study. CIRB helpdesk surveys measure satisfaction of helpdesk users and is conducted occasionally or each time the person contacts the helpdesk. *Frequency of Response:* Once, except for the SAE Reviewer Worksheet. *Affected Public:* Includes the Federal Government, business or other for-profits and not-for-profit institutions. *Type of Respondents:* Respondents include any customer who contacts the CIRB Helpdesk, institutional review board members and CIRB review participants. The annual reporting burden is estimated at 2209 hours (*see* Table 1 below for the estimated time burden). The total burden has decreased slightly as a result of corrected calculations from what was published in the 60-Day **Federal Register** Notice. The average annual cost to the government over a 12-month period is approximately $153,574 per year for a six year contract. This includes total annualized capital/start up costs of $25,108 and operating costs of $150,637.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (min/hr)	Annual burden hours
Participants/Board Members.	CIRB Helpdesk Survey (Attachment 1)	1,500	1	10/60 (.17 hour)	250
Participants	NCI CIRB Institution Enrollment Worksheet (Attachment 2A).	30	1	3.5 hours	105
Participants	IRB Staff at Signatory Institution's IRB (Attachment 2B).	65	1	10/60 (.17 hour)	11
Participants	Investigator at Signatory Institution (Attachment 2C).	65	1	10/60 (.17 hour)	11
Participants	Research Staff at Signatory Institution (Attachment 2D).	65	1	10/60 (.17 hour)	11
Participants	Investigator at Affiliate Institution (Attachment 2E).	65	1	10/60 (.17 hour)	11
Participants	Research Staff at Affiliate Institution (Attachment 2F).	65	1	10/60 (.17 hour)	11
Participants	IRB at Signatory Institution (Attachment 2G)	65	1	10/60 (.17 hour)	11
Participants	Component Institution at Signatory Institution (Attachment 2H).	65	1	10/60 (.17 hour)	11
Participants	IRB at Affiliate Institution (Attachment 2I)	65	1	10/60 (.17 hour)	11
Participants	Institution Affiliate Institution without an IRB (Attachment 2J).	65	1	10/60 (.17 hour)	11
Participants	Request for 30–Day Access Form (Attachment 2K).	50	1	10/60 (.17 hour)	8
Participants	Facilitated Review (FR) Acceptance Form (Attachment 2L).	1,450	1	10/60 (.17 hour)	242
Participants	Study Review Responsibility Transfer Form (Attachment 2M).	120	1	10/60 (.17 hour)	20
Board Members	CIRB New Board Member Biographical Sketch Form (Attachment 3B).	16	1	30/60 (.5 hour)	8
Board Members	CIRB New Board Member Contact Information Form (Attachment 3C).	16	1	15/60 (.25 hour)	4
Board Members	CIRB New Board Member W–9 (Attachment 3D).	16	1	15/60 (.25 hour)	4
Board Members	CIRB New Board Member Non-Disclosure Agreement (NDA) (Attachment 3E).	16	1	15/60 (.25 hour)	4
Board Members	Direct Deposit Form (Attachment 4)	16	1	15/60 (.25 hour)	4
Participants	NCI Adult CIRB Application (Attachment 5A).	150	1	2 hours	300
Participants	NCI Pediatric CIRB Application (Attachment 5B).	62	1	2 hours	124
Participants	Adult/Pediatric CIRB Application—Ancillary Studies (Attachment 5C).	10	1	2 hours	20
Participants	Summary of CIRB Application Revisions (Attachment 5D).	20	1	30/60 (.5 hour)	10
Participants	Adult/Pediatric CIRB Application for Continuing Review (Attachment 5E).	230	1	1 hour	230
Board Members	Adult CIRB Reviewer Findings—Initial Review of Cooperative Group Protocol (Attachment 6A).	20	1	4 hours	80

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