ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Data collection mechanism	Number of respondents	Average burden per response (in hours)	Total Burden (in hours)
Private Sector Partners	Focus group	32	1	32
	Web-based survey	120	30/60	60
	Interview	120	1	120
	Focus group	48	1	48
Total				415

Dated: December 5, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–29399 Filed 12–11–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–09–07AB]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov*. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Measuring the Psychological Impact on Communities Affected by Landmines—New—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this project is to conduct focus groups and an observational baseline survey that assesses the effectiveness of Humanitarian Mine Action (landmine and unexploded ordnance clearance, also known as de-mining) upon the economic, social and mental well being of impacted communities.

This work will be conducted by the Harvard Humanitarian Initiative, a center of Harvard University, under a cooperative agreement with CDC. The study will examine the impact that individuals and communities in these locations suffer when living in an area with landmines and unexploded ordnance (UXO). Individuals and communities also suffer from the lack of use of all land resources as well as the trauma of injured or killed family members.

This research on the impact of demining is necessary because landmines and UXO continue to negatively impact civilian populations. For example, it has been estimated that each year landmines and unexploded ordnance lead to the injury and death of 24,000 persons worldwide, predominately civilians. At the same time, it is estimated that civilians account for 35% to 65% of war-related deaths and injuries. The use of landmines and UXO is ongoing, and therefore this issue merits continued attention.

Up to this point, however, little if any of the international response to landmines has studied the economic, social, and mental impact upon a community. Instead the focus has been their physical impact in terms of numbers of injured and killed. There are no statistics nor is there research that can accurately capture these alternative measures of impact.

There now exists an opportunity for further research that will benefit the general public as well as the organizations and governments working with persons impacted by landmines and UXO. The proposed work will allow CDC to continue its commitment to reduce the negative health impact posed by landmines and unexploded ordnance, both for U.S. and non-U.S.-based populations. Approximately 1,264 respondents will come from the Lebanon area. The estimates of annualized burden hours for the household surveys and the focus groups are shown in the table below.

There are no costs to respondents except their time to participate in the survey. The total estimated annualized burden hours are 1,328.

ESTIMATED ANNUALIZED BURDEN

Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Household Survey—Cluster munitions	600	1	1
Household Survey Control—Remote landmines	600	1	1
Focus Group—Cluster munitions	32	1	2
Focus Group Control—Remote landmines	32	1	2

Dated: December 2, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–29402 Filed 12–11–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0499]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by January 12, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira_submissions@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0625. Also include the FDA 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.

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.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), (including the submission of updated information), be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. FDA expects 20,000 to 30,000 device establishments to begin registering electronically at that time.

Section 222 of FDAAA amends section 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

In the **Federal Register** of October 1, 2008 (73 FR 57106), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the 2007 Amendments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
222[2]	3673	2,600	1	2,704	0.5	1,352
223[2]	3673	24,382	1	24,382	0.25	6,095
224[2]		29,370	1	29,370	0.75	22,028
224[3]		2,600	1	2,600	0.5	1,300
224 (waiver request)[2]		20	1	20	1	20
224 (waiver request)[3]		1	1	1	1	1
Total Hours						30,796

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual increase in burden.