

Respondents: Executive directors and key staff of faith based and community organizations that received three-year CEY grants beginning in 2007.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Lead Organization Executive Director	10	1	3.5	35
Lead Organization Key Staff	20	1	2.5	50
Partner Organization Executive Director	60	1	3.5	210
Partner Organization Key Staff	60	1	2.5	150

Estimated Total Annual Burden Hours: 445.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address:

OPREInfoCollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, FAX: 202-395-6974, Attn: Desk Officer for ACF.

Dated: July 2, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2006-N-0364] (formerly Docket Nos. 2006N-0466 and FDA-2007-0650)

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of the Chief Information Officer (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 28, 2007 (72 FR 73589), 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 0910-0614. The approval expires on June 30, 2011. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-N-0464] (formerly Docket No. 2005N-0403)

Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing." This draft guidance document establishes a Pilot Program for industry to voluntarily submit drug establishment registration and drug listing information in an electronic format that FDA can process, review, and archive. The document provides guidance on what required and FDA-recommended information related to drug establishment registration and drug listing to submit and on how to electronically prepare and submit the information to FDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance, including comments regarding proposed collection of information, by September 9, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF-18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests.