

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services is proposing an information collection activity as part of a study of responsible fatherhood prisoner reentry pilot programs. This information collection will involve discussion of a range of topics with key informants in

grantee and partner organizations such as their organizational structure, program services, populations served, and specific approaches under the grant programs, as well as with individuals who participate, eligible nonparticipants, and family members about their circumstances and experiences.

Respondents: Semi-structured discussions will be held with administrators, managers and staff of responsible fatherhood prisoner reentry grant programs and of key partner or community agencies. Information may also be collected from participants, eligible non-participants, and family members.

ANNUAL BURDEN ESTIMATES

| Instrument | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|-------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------------|
| Discussion Guides | 150 | 1 | 1 | 150 |

Estimated Total Annual Burden Hours: 150.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. *E-mail address:* OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 20, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0322]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requests for Inspection Under the Inspection by Accredited Persons Program

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 October 26, 2011.

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:* 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0569. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleston@fda.hhs.gov.

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.

Requests for Inspection Under the Inspection by Accredited Persons Program—(OMB Control Number 0910-0569)—(Extension)

Section 201 of the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250) amended section 704 of the Federal Food, Drug, and Cosmetic Act by adding subsection (g) (21 U.S.C. 374(g)). This amendment authorized FDA to establish a voluntary third-party inspection program applicable to manufacturers of class II or class III medical devices who meet certain eligibility criteria. In 2007, the program was modified by the Food and Drug Administration Amendments Act of 2007 by revising eligibility criteria and by no longer requiring prior approval by FDA. To reflect the revisions, FDA modified the title of the collection of information and on March 2, 2009, issued a guidance entitled "Manufacturer's Notification of the Intent to Use an Accredited Person Under the Accredited Persons Inspection Program Authorized by Section 228 of the Food and Drug Administration Amendments Act of 2007." This guidance supersedes the Agency's previous guidance regarding requests for third-party inspection and may be found on the Internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085187.htm>. This guidance is intended to assist device establishments in determining whether they are eligible to participate in the Accredited Persons (AP) Program and, if so, how to submit notification of their intent to use the program. The AP Program applies to manufacturers who currently market their medical devices in the United States and who also market or plan to market their devices in foreign countries. Such

manufacturers may need current inspections of their establishments to operate in global commerce.

There are approximately 8,000 foreign and 10,000 domestic manufacturers of medical devices. Approximately 5,000 of these firms only manufacture class I devices and are, therefore, not eligible for the AP Program. In addition, 40 percent of the domestic firms do not export devices and therefore are not

eligible to participate in the AP Program. Further, 10 to 15 percent of the firms are not eligible due to the results of their previous inspection. FDA estimates there are 4,000 domestic manufacturers and 4,000 foreign manufacturers that are eligible for inclusion under the AP Program. Based on communications with industry, FDA estimates that on an annual basis approximately 100 of these

manufacturers may use an AP in any given year.

In the **Federal Register** of May 23, 2011 (76 FR 29764), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| 21 U.S.C. section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 374(g) | 100 | 1 | 100 | 15 | 1,500 |

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

Dated: September 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-24582 Filed 9-23-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0275]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

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 October 26, 2011.

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: 202-395-7285, or e-mailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0616. Also include the FDA docket number found

in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3794,

Jonnalynn.capezzuto@fda.hhs.gov.

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. Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)—(OMB Control Number 0910-0616)—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and is already approved by OMB. The OMB control numbers and expiration dates for submitting Form FDA 3674 under the following parts are: 21 CFR parts 312 and 314 (human drugs) are 0910-0014, expiring August 31, 2011, and 0910-0001, expiring May 31, 2011; 21 CFR parts 312 and 601 (biological products) are 0910-0014 and 0910-0338, expiring December 31, 2011; 21 CFR parts 807 and 814 (devices) are 0910-0120, expiring December 31, 2013, and 0910-0231, expiring December 31, 2013.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-85) amended the PHS Act by adding section 402(j) (42 U.S.C. 282(j)). The provisions require additional information to be submitted to the clinical trials data bank

(<http://ClinicalTrials.gov>)¹ previously established by the National Institutes of Health (NIH)/National Library of Medicine, including expanded information on clinical trials and information on the results of clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers.

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement.

The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed

¹ FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.