The Food and Drug Administration

Federal Food, Drug, and Cosmetic Act.''

Implementation of Section 505(o) of the

Studies and Clinical Trials—

industry entitled "Postmarketing

availability of a draft guidance for

Administration (FDA) is announcing the

HHS.

technology. Written comments should

use of automated collection techniques

on respondents, including through the

collected; and (d) ways to minimize the

clarity of the information to be

ways to enhance the quality, utility, and

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)

ways to enhance the quality, utility, and

or other forms of information

burden of the collection of information on

respondents, including through the

use of automated collection techniques

or forms of information

technology. Written comments should

be received within 60 days of this

notice.

SUMMARY:

The American Recovery and

Reinvestment Act of 2009 (ARRA)

Performance Progress Report—New—

Office of the Chief Operating Officer

(COO), Centers for Disease Control and

Prevention (CDC).

Background and Brief Description

The American Recovery and

Reinvestment Act of 2009 was signed

into law on February 17, 2009, Public

Law 111–5 ("Recovery Act"). The

purpose of this proposed data collection

is to collect quarterly performance

information for all CDC grants and

cooperative agreements funded under

the Recovery Act. This will allow CDC

to receive reports on recipient

performance measures as set forth in the

applicable Funding Opportunity

Announcement (FOA) and Notice of

Grant Award. This requirement is in

addition to the reporting requirements

of Section 1512 of the Recovery Act, set

forth by the Office of Management and

Budget (OMB) under the data collection

instrument titled “Standard Data

Elements for Reports under Section

1512 of the American Recovery and

Reinvestment Act of 2009, Public Law

111–5 (Grants, Cooperative Agreements

and Loans).”

The form CDC proposes to use is a

modified Performance Progress Report

(SF–PPR) which was successfully

piloted by the Administration for

Children and Families (ACF). CDC

intends to use this modified form for

quarterly standard reporting of

performance measures set forth in the

applicable FOA and Notice of Grant

Award for all CDC Recovery Act funded

grants and cooperative agreements.

In addition to allowing for uniformity of

information collection, this format will

support systematic electronic collection

and submission of information. The

form contains identifying data elements

and a section for a performance

narrative.

There are no costs to respondents

other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

<table>
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<tr>
<th>Respondents</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response (in hours)</th>
<th>Total burden (in hours)</th>
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<td>405</td>
<td>4</td>
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<td>2430</td>
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</table>

Dated: July 8, 2009.

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

[FR Doc. E9–16772 Filed 7–14–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0283]

Draft Guidance for Industry on Postmarketing Studies and Clinical Trials—Implementation of the Federal Food, Drug, and Cosmetic Act; 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 "Postmarketing Studies and Clinical Trials—Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act." The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) authorizing FDA to require certain postmarketing studies and clinical trials for prescription drugs and biological products approved under the act or the Public Health Service Act (the PHS Act). This draft guidance provides information on the implementation of the new provisions and a description of the types of postmarketing studies and clinical trials that will generally be required under the new legislation (postmarketing requirements [PMRs]) and the types that will generally be agreed-upon commitments (postmarketing commitments [PMCs]) because they do not meet the new statutory criteria for required postmarketing studies and clinical trials.

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 comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 13, 2009.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy Clark, Center for Drug Evaluation and Research, Food and Drug
will be required (PMRs) under section 505(o) of the act and which types will be agreed-upon commitments because they do not meet the statutory criteria for required studies and trials (PMCs).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on the implementation of section 901 of FDAAA on postmarketing studies and clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance provides information on the implementation of section 901 of FDAAA. The collections of information requested in the draft guidance would be submitted under 21 CFR 314.80, 314.81, and 601.70. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and are approved under OMB control numbers 0910–0338, 0910–0653, 0910–0673, and 0910–0688. Section VI of the draft guidance refers to procedures in the guidance entitled “Formal Dispute Resolution: Appeals Above the Division Level,” which contains collections of information approved under OMB control number 0910–0430.

IV. Electronic Access