plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333; or send an e-mail to *omb@cdc.gov*.

Comments are invited 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) ways to enhance 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. Written comments should be received within 60 days of this notice.

Proposed Project

CDC American Recovery and Reinvestment Act of 2009 (ARRA) Performance Progress Report—New—Office of the Chief Operating Officer (OCOO), 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

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Recipients using CDC ARRA Performance Progress Report	405	4	1.5	2430

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 by 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

Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6144, Silver Spring, MD 20993–0002, 301–796–5400; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

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.'' In the past, FDA has used the term ''PMC'' to refer to studies (including clinical trials), conducted by an applicant after FDA has approved a drug for marketing or licensing, that were intended to further refine the safety, efficacy, or optimal use of a product, or to ensure consistency, and reliability of product quality. These commitments were either agreed upon by FDA and the applicant or, in certain circumstances, required by FDA. Prior to the passage of FDAAA, FDA required PMCs in the following situations:

- Subpart H and subpart E accelerated approvals, which require postmarketing studies to demonstrate clinical benefit (21 CFR 314.510 and 601.41);
- Deferred pediatric studies, where studies are required under the Pediatric Research Equity Act (PREA) (21 CFR 314.55(b) and 601.27(b)); and
- Animal Efficacy Rule approvals, where studies to demonstrate safety and efficacy in humans are required at the time of use (21 CFR 314.610(b)(1) and 601.91(b)(1)).

Title IX, section 901 of FDAAA (Public Law 110–85) amended the act by adding new section 505(o) (21 U.S.C. 355(o)). Section 505(o) of the act authorizes FDA to require certain postmarketing studies or clinical trials for prescription drug and biological products approved under section 505 of the act or section 351 of the PHS Act (42 U.S.C. 262). Section 505(o)(3)(B) of the act states that postmarketing studies and clinical trials may be required for one of three purposes:

- To assess a known serious risk related to the use of the drug;
- To assess signals of serious risk related to the use of the drug; or
- To identify an unexpected serious risk when available data indicates the potential for a serious risk.

This draft guidance provides information on the implementation of new section 505(o) of the act. The draft guidance also describes which types of postmarketing studies and clinical trials 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 0910–0230, 0910–0001, and 0910–0338. 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

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *http://www.regulations.gov*.

Dated: July 2, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0021 (formerly Docket No. 1998D–0514)]

Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''ANDAs: Impurities in Drug Substances,'' which is a revision of a guidance for industry of the same name that published in November 1999. The guidance provides recommendations for applicants on what chemistry, manufacturing, and controls (CMC) information to include regarding the reporting, identification, and qualification of impurities in drug substances produced by chemical synthesis when submitting original abbreviated new drug applications (ANDAs); drug master files (DMFs), including type II DMFs; and ANDA supplements for changes in the synthesis or processing of a drug substance.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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 guidance document.