(2) Coordinates, develops, and/or provides program integrity related communications, outreach, and training;

(3) Oversees, monitors, and follows-up on program integrity risk assessments;

(4) Develops tools and guidance regarding program integrity and provides technical assistance and direction to HHS Divisions on enhancing program integrity;

(5) Shares program integrity related best practices and other activities that improve program integrity;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders on program integrity related activities; and

(7) Leads other activities that enhance HHS program integrity and integrate it into business operations.

b. *Division of Analytics, Research and Evaluation (AMS32).* The Division:

(1) Provides support for the Department's program integrity governance structure;

(2) Analyzes, evaluates, coordinates, tracks, and provides quality control/quality assurance on program integrity related information;

(3) Identifies evidenced-based program integrity practices and leverages results to recommend solutions to program integrity challenges;

(4) Develops communication resources to facilitate program integrity outreach;

(5) Develops and leverages innovative approaches, using innovative tools and technology, to enhance HHS program integrity;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders on program integrity analytics and solutions; and

(7) Leads other activities that enhance program integrity related analytics and problem solving.

c. *Division of Payment Accuracy Improvement (AMS33).* The Division:

(1) Implements the Improper Payments Information Act of 2002, the Improper Payments Elimination and Recovery Act of 2010, the Improper Payments Elimination and Recovery Improvement Act of 2012, and improper payment related Executive Orders and other regulatory requirements;

(2) Provides analysis of high risk programs and coordinates error rate measurements and improvements for high risk programs;

(3) Coordinates efforts among HHS Divisions to recapture improper payments;

(4) Identifies and shares best practices on addressing improper payments with HHS leadership, HHS Divisions, OMB, and other agencies;

(5) Participates in inter-agency and HHS workgroups to address improper payments;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, OMB and other stakeholders on improper payment initiatives; and

(7) Leads other activities that support improving payment accuracy.

d. *Division of Audit Resolution (AMS34).* The Division:

(1) Reviews, resolves, and coordinates, where necessary, the audit findings of grantees affecting the programs of more than one HHS Division or Federal agency;

(2) Coordinates and provides technical assistance to grantees and HHS Divisions on all aspects of audit resolution in an effort to reduce the number and significance of audit findings;

(3) Works with HHS' Single Audit Coordinator to streamline and enhance the efficiency of the audit resolution process;

(4) Establishes and monitors Department policies regarding audit resolution, as required by OMB Circular A–50 and other OMB or regulatory guidance;

(5) Prepares the Management Report on Final Action for the Department's annual Agency Financial Report;

(6) Prepares reports, briefings, and makes recommendations to senior HHS leadership, HHS Divisions, and other stakeholders regarding audit resolution activities; and

(7) Leads other activities that support and advance audit resolution.

Dated: August 15, 2013.

E.J. Holland, Jr.,

Assistant Secretary for Administration.

[FR Doc. 2013–20525 Filed 8–21–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0150]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

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 (the PRA).

DATES: Fax written comments on the collection of information by September 23, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0670. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims—(OMB Control Number 0910–0670)—Extension

This guidance is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension. With few exceptions, current labeling for antihypertensive drugs includes only the information that these drugs are indicated to reduce blood pressure; the labeling does not include information on the clinical benefits related to cardiovascular outcomes expected from such blood pressure reduction. However, blood pressure control is well established as beneficial in preventing serious cardiovascular events, and inadequate treatment of hypertension is acknowledged as a significant public health problem. FDA believes that the appropriate use of these drugs can be encouraged by making the connection between lower blood pressure and improved cardiovascular outcomes more explicit in labeling. The intent of the guidance is to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data. The guidance encourages applicants to

submit labeling supplements containing the new language.

The guidance contains two provisions that are subject to OMB review and approval under the PRA, and one provision that would be exempt from OMB review:

(1) Section IV.C of the guidance requests that the CLINICAL STUDIES section of the Full Prescribing Information of the labeling should include a summary of placebo or active-controlled trials showing evidence of the specific drug's effectiveness in lowering blood pressure. If trials demonstrating cardiovascular outcome benefits exist, those trials also should be summarized in this section. Table 1 in section V of the guidance contains the specific drugs for which the FDA has concluded that such trials exist. If there are no cardiovascular outcome data to cite, one of the following two paragraphs should appear:

''There are no trials of [DRUGNAME] or members of the [name of pharmacologic class] pharmacologic class demonstrating reductions in cardiovascular risk in patients with hypertension,'' or ''There are no trials of [DRUGNAME] demonstrating reductions in cardiovascular risk in patients with hypertension, but at least one pharmacologically similar drug has demonstrated such benefits.''

In the latter case, the applicant's submission generally should refer to table 1 in section V of the guidance. If the applicant believes that table 1 is incomplete, it should submit the clinical evidence for the additional information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. FDA estimates that no more than one submission to the docket will be made annually from one company, and that each submission will take approximately 10 hours to prepare and submit. Concerning the recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling, FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) require such labeling, and the information collection associated with these regulations is approved by OMB under OMB control number 0910–0572.

(2) Section VI.B of the guidance requests that the format of cardiovascular outcome claim prior approval supplements submitted to FDA under the guidance should include the following information:

1. A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150.

2. Applicable FDA forms (e.g., 356h, 3397).

3. Detailed table of contents.

4. Revised labeling:

a. Include draft revised labeling conforming to the requirements in §§ 201.56 and 201.57;

b. Include marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission.

FDA estimates that approximately 20 cardiovascular outcome claim supplements will be submitted annually from approximately 8 different companies, and that each supplement will take approximately 20 hours to prepare and submit. The guidance also recommends that other labeling changes (e.g., the addition of adverse event data) should be minimized and provided in separate supplements, and that the revision of labeling to conform to §§ 201.56 and 201.57 may require substantial revision to the ADVERSE REACTIONS or other labeling sections.

(3) Section VI.C of the guidance states that applicants are encouraged to include the following statement in promotional materials for the drug.

''[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.''

The inclusion of this statement in the promotional materials for the drug would be exempt from OMB review based on 5 CFR 1320.3(c)(2), which states that ''The public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not included * * *'' within the definition of ''collection of information.''

In the **Federal Register** of April 18, 2013 (78 FR 23271), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	8	2.5	20	20	400
Total					410

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

Dated: August 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–20471 Filed 8–21–13; 8:45 am]

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