

maximize C2C's impact. The next three years will be dedicated to implementing the evaluation described in this submission. We are proposing four data collection activities: (1) A cross-sectional survey of organizations that have ordered and used the materials with consumers; (2) A cross-sectional survey of consumers, drawn from the Knowledge Networks panel, to measure the association between C2C and consumer knowledge and behavior; (3) semi-structured interviews with staff from a limited set of community organizations as part of a case study; and (4) focus groups of consumers as part of a case study. The case study will be conducted in a community where English is not the preferred language, and where C2C materials in another language (e.g., Spanish, Arabic, Chinese, Haitian Creole, Korean, Russian, and Vietnamese) were used with consumers. *Form Number:* CMS-10632 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,460; *Total Annual Responses:* 3,460; *Total Annual Hours:* 1,176. (For policy questions regarding this collection contact Ashley Peddicord-Austin at 410-786-0757).

Dated: October 28, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0117]

#### 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 or we) 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 December 2, 2016.

**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.

#### 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 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:

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

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

- Detailed table of contents.

- Revised labeling to:

- Include draft revised labeling conforming to the requirements in §§ 201.56 and 201.57 and

- 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 1 cardiovascular outcome claim supplement will be submitted annually from approximately 1 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 February 22, 2016 (81 FR 8726), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Submission to Docket No. FDA-2008-D-0150 .....	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission ...	1	1	1	20	20
<b>Total</b> .....					<b>30</b>

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

Dated: October 27, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2004-D-0369]

**Animal Drug User Fees and Fee Waivers and Reductions; Draft Revised Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft revised guidance for industry (GFI) #170 entitled “Animal Drug User Fees and Fee Waivers and Reductions.” This draft revised guidance document describes the types of fees the Food and Drug Administration (FDA or the Agency) is authorized to collect under the Animal Drug User Fee Act of 2003 (ADUFA), as amended, and how to request waivers and reductions from these fees.

**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 revised guidance before it begins work on the final version of the guidance,

submit either electronic or written comments on the draft revised guidance by January 3, 2017.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2004-D-0369 for “Animal Drug User Fees and Fee Waivers and Reductions.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The