TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Production and process changes and environmental control–820.70(b) and (c)	27,074	1	27,074	2	54,148
Personnel–820.70(d)	27,074	1	27,074	3	81,222
Contamination control–820.70(e)	27,074	1	27,074	2	54,148
Equipment maintenance schedule, inspection, and adjustment–820.70(g)(1)–(3)	27,074	1	27,074	1	27,074
Manufacturing material–820.70(h)	27,074	1	27,074	2	54,148
Automated processes–820.70(i)	27,074	1	27,074	8	216,592
Control of inspection, measuring, and test equipment–820.72(a)	27,074	1	27,074	5	135,370
Calibration procedures, standards, and records–820.72(b)(1)–(2)	27,074	1	27,074	1	27,074
Process validation–820.75(a)	27,074	1	27,074	3	81,222
Validated process parameters, monitoring, control methods, and data–820.75(b)	27,074	1	27,074	1	27,074
Revalidation–820.75(c)	27,074	1	27,074	1	27,074
Acceptance activities–820.80(a)–(e)	27,074	1	27,074	5	135,370
Acceptance status–820.86	27,074	1	27,074	1	27,074
Control of nonconforming product–820.90(a)	27,074	1	27,074	5	135,370
Nonconforming product review/disposition procedures and rework procedures–820.90(b)(1)–(2)	27,074	1	27,074	5	135,370
Procedures for corrective/preventive actions–820.100(a)(1)–(7)	27,074	1	27,074	12	324,888
Corrective/preventive activities–820.100(b)	27,074	1	27,074	1	27,074
Labeling procedures–820.120(b)	27,074	1	27,074	1	27,074
Labeling documentation–820.120(d)	27,074	1	27,074	1	27,074
Device packaging–820.130	27,074	1	27,074	1	27,074
Handling–820.140	27,074	1	27,074	6	162,444
Storage–820.150(a) and (b)	27,074	1	27,074	6	162,444
Distribution procedures and records–820.160(a) and (b)	27,074	1	27,074	1	27,074
Installation–820.170	27,074	1	27,074	2	54,148
Record retention period–820.180(b) and (c)	27,074	1	27,074	2	54,148
Device master record–820.181	27,074	1	27,074	1	27,074
Device history record–820.184	27,074	1	27,074	1	27,074
Quality system record–820.186	27,074	1	27,074	1	27,074
Complaint files–820.198(a)–(g)	27,074	1	27,074	5	135,370
Servicing procedures and reports–820.200(a) and (d)	27,074	1	27,074	3	81,222
Statistical techniques procedures and sampling plans–820.250	27,074	1	27,074	1	27,074
Total					9,421,752

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

Our estimated burden for the information collection reflects an overall increase of 812,928 hours. We attribute this adjustment to an increase in the number of respondents.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24805 Filed 11–14–19; 8:45 am]

BILLING CODE 4164–01–P

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; 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.

DATES: Fax written comments on the collection of information by December 16, 2019.

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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601

Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims OMB Control Number 0910–0670—Extension

This information collection request supports recommendations found in Agency guidance. The document entitled, ''Guidance for Industry; Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims,'' available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hypertension-indication-drug-labeling-cardiovascular-outcome-claims,* encourages the submission of supplemental labeling and is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension, and to provide common labeling for antihypertensive drugs except where differences are clearly supported by clinical data.

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. We believe 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.

As discussed in the guidance, we therefore recommend the following information collection:

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. We estimate 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. Recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling are covered by FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) and require such labeling. The information collection associated with these regulations is approved under OMB control number 0910–0572.

2. Section VI.B of the guidance requests that the format of the cardiovascular outcome claim submitted to FDA in a prior approval supplement 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
  - 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.

We estimate that on average, 4 cardiovascular outcome claim supplements will be submitted annually from 4 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 the drug's promotional materials:

- ''[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Controlling 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 is exempt from OMB review under 5 CFR 1320.3(c)(2).

In the **Federal Register** of July 16, 2019 (84 FR 33952), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

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	4	1	4	20	80

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Total					90

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

Our estimate for the information collection reflects an overall increase of burden. This increase corresponds to an increase in submissions we have received over the last few years.

Dated: November 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–24780 Filed 11–14–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0350]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Tobacco Retailers on Tobacco Retailer Training Programs

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 December 16, 2019.

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 0910–0745. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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 Tobacco Retailers on Tobacco Retailer Training Programs

OMB Control Number 0910–0745—Extension

I. Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) does not require retailers to implement retailer training programs. However, the statute does provide for lesser civil money penalties for violations of access, advertising, and promotion restrictions of regulations issued under section 906(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, for retailers who have implemented a training program that complies with standards developed by FDA for such programs. FDA intends to issue regulations establishing standards for approved retailer training programs. In the interim, the guidance is intended to assist tobacco retailers in implementing effective training programs for employees.

The guidance discusses recommended elements that should be covered in a training program, such as: (1) Federal laws restricting the access to, and the advertising and promotion of, cigarettes, smokeless, and covered tobacco products; (2) the health and economic effects of tobacco use, especially when the tobacco use begins at a young age; (3) written company policies against sales to minors and other restrictions on the access to, and the advertising and promotion of, tobacco products; (4) identification of the tobacco products sold in the retail establishment that are subject to the Federal laws prohibiting their sale to persons under the age of 18; (5) age verification methods; (6) practical guidelines for refusing sales; and (7) testing to ensure that employees have the required knowledge. The guidance recommends that retailers require current and new employees to take a written test prior to selling tobacco products and that refresher training be provided at least annually and more frequently as needed. The guidance recommends that retailers maintain certain written records documenting that all individual employees have been trained and that retailers retain these records for 4 years in order to be able to provide evidence of a training program during the 48-month time period covered by the civil money penalty schedules in section 103(q)(2)(A) of the Tobacco Control Act.

The guidance also recommends that retailers implement certain hiring and management practices as part of an effective retailer training program. The guidance suggests that applicants and current employees be notified both verbally and in writing of the importance of complying with laws prohibiting the sales of tobacco products to persons under the age of 18. In addition, FDA recommends that retailers implement an internal compliance check program and document the procedures and corrective actions for the program.

In the **Federal Register** of June 17, 2019 (84 FR 28059), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received that was PRA related.

The comment suggested that FDA should adjust the burden calculation for two areas, develop training programs and review and updating training programs. The comment suggested that it would reasonably take 1000 hours to develop a training program. FDA disagrees with this comment and does not intend to adjust the burden calculations for these areas. FDA has not made significant changes to this guidance and expects that many retailer training programs already meet the elements in the guidance, some retailers would update their training program to meet the elements in the guidance, and a smaller number of other retailers would develop a training program for the first time. FDA has not received any comments from affected retailers regarding the time needed to develop retailer training programs, or that the burden calculation was insufficient. Additionally, FDA has provided several resources, such as webinars and