private organizations, and that have as their primary purpose the operation of shelters for victims of family violence, domestic violence, and dating violence, and their dependents or those which provide counseling, advocacy, and self-help services to victims of family violence, domestic violence, and dating violence, and their dependents (Section 10407(a)(2)(B)(iii)).

(4) Not less than 70 percent of the funds distributed shall be for the primary purpose of providing immediate shelter and supportive services to adult and youth victims of family violence, domestic violence, or dating violence, and their dependents (Section 10408(b)(2)).

(5) Not less than 25 percent of the funds distributed shall be for the purpose of providing supportive services and prevention services as described in Section 10408(b)(2)to victims of family violence, domestic violence, or dating violence, and their dependents).

(6) Not more than 5 percent of the funds will be used for State administrative costs (Section 10407(a)(2)(b)(i)).

(7) The State grantee is in compliance with the statutory requirements of Section 10407(a)(2)(C), regarding the equitable distribution of grants and grant funds within the State and between urban and rural areas within the State.

(8) The State will consult with and provide for the participation of the State Domestic Violence Coalition in the planning and monitoring of the distribution of grant funds and the administration of the grant programs and projects (Section 10407(a)(2)(D)).

(9) Grant funds made available under this program by the State will not be used as direct payment to any victim of family violence, domestic violence, or dating violence, or to any dependent of such victim (Section 10408(d)(1)).

(10) No income eligibility standard will be imposed on individuals with respect to eligibility for assistance or services supported with funds appropriated to carry out the FVPSA (Section 10406(c)(3)).

(11) No fees will be levied for assistance or services provided with funds appropriated to carry out the FVPSA (Section 10406(c)(3)).

(12) The address or location of any shelter or facility assisted under the FVPSA that otherwise maintains a confidential location will, except with written authorization of the person or persons responsible for the operation of such shelter, not be made public (Section 10406(c)(5)(H)).

(13) The applicant has established policies, procedures, and protocols to ensure compliance with the provisions of Section 10406(c)(5) regarding non-disclosure of confidential or private information (Section 10407(a)(2)(A)).

(14) Pursuant to Section 10406(c)(5), the applicant will comply with requirements to ensure the non-disclosure of confidential or private information, which include, but are not limited to: (1) Grantees will not disclose any personally identifying information collected in connection with services requested (including services utilized or denied), through grantee's funded activities or reveal personally identifying information without informed, written, reasonably time-limited consent by the person about whom information is sought, whether for the FVPSA-funded activities or any other Federal or State program and in accordance with Section 10406(c)(5)(B)(ii); (2) grantees will not release information compelled by statutory or court order unless adhering to the requirements of Section10406(c)(5)(C); (3) grantees may share non-personally identifying information in the aggregate for the purposes enunciated in Section 10406(c)(5)(D)(i) as well as for other purposes found in Section 10406(c)(5)(D)(ii) and (iii).

(15) Grants funded by the State in whole or in part with funds made available under the FVPSA will prohibit discrimination on the basis of age, disability, sex, race, color, national origin, or religion (Section 10406(c)(2)).

(16) Funds made available under the FVPSA will be used to supplement and not supplant other Federal, State, and local public funds expended to provide services and activities that promote the objectives of the FVPSA (Section 10406(c)(6)).

(17) Receipt of supportive services under the FVPSA will be voluntary. No condition will be applied for the receipt of emergency shelter as described in Section 10408(d)(2)).

(18) The State grantee has a law or procedure to bar an abuser from a shared household or a household of the abused person, which may include eviction laws or procedures (Section 10407(a)(2)(H)).

Signature

Title

Organization

Appendix B

LGBTQ Accessibility Policy

As the Authorized Organizational Representative (AOR) signing this application on behalf of *[Insert full, formal name of applicant organization]*

I hereby attest and certify that:

The needs of lesbian, gay, bisexual, transgender, and questioning program participants are taken into consideration in applicant's program design. Applicant considered how its program will be inclusive of and non-stigmatizing toward such participants. If not already in place, awardee and, if applicable, sub-awardees must establish and publicize policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin. The submission of an application for this funding opportunity constitutes an assurance that applicants have or will put such policies in place within 12 months of the award. Awardees should ensure that all staff members are trained to prevent and respond to harassment or bullying in all forms during the award period. Programs should be prepared to monitor claims, address them seriously, and document their corrective action(s) so all participants are assured that programs are safe, inclusive, and non-stigmatizing by design and in operation. In addition, any sub-awardees or subcontractors:

- Have in place or will put into place within 12 months of the award policies prohibiting harassment based on race, sexual orientation, gender, gender identity (or expression), religion, and national origin;
- Will enforce these policies;
- Will ensure that all staff will be trained during the award period on how to prevent and respond to harassment or bullying in all forms, and;
- Have or will have within 12 months of the award, a plan to monitor claims, address them seriously, and document their corrective action(s).

Insert Date of Signature:
Print Name and Title of the AOR:
Signature of AOR:

[FR Doc. 2013–08711 Filed 4–17–13; 8:45 am]

BILLING CODE 4184–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0150]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the guidance ''Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims,'' which is intended to assist applicants in developing labeling for outcome claims for drugs that are indicated to treat hypertension.

DATES: Submit either electronic or written comments on the collection of information by June 17, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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:

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.''

FDA requests public comments on the information collection provisions described in this document and set forth in the following table:

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 Number 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: April 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–09093 Filed 4–17–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2001–P–0238, FDA–2010–P–0526, FDA–2010–P–0540, FDA–2011–P–0473]

Determination That the OXYCONTIN (Oxycodone Hydrochloride) Drug Products Covered by New Drug Application 20–553 Were Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that OXYCONTIN (oxycodone hydrochloride) extended-release tablets (10 milligrams (mg), 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg) approved under new drug application (NDA) 20–553 were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for products that reference NDA 20–553.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6368, Silver Spring, MD 20993–0002, 301–796–3522.

SUPPLEMENTARY INFORMATION:

I. Background

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 U.S.C. 355(j)(7)(C); 21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made before approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

OXYCONTIN (oxycodone hydrochloride) extended-release tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg (original OxyContin), are the subject of NDA 20–553, held by Purdue Pharma LP (Purdue) and initially approved on December 12, 1995. A reformulated version of these products, OXYCONTIN (oxycodone hydrochloride) extended-release tablets, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg (reformulated OxyContin), are the subject of NDA 22–272, also held by Purdue and initially approved on April 5, 2010. Reformulated OxyContin was developed with physicochemical properties that are intended to make the tablet more difficult to manipulate for purposes of abuse or misuse. Both original and reformulated OxyContin are opioid agonist products indicated for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

In correspondence dated August 10, 2010, Purdue notified FDA that it had ceased shipment of original OxyContin, and FDA subsequently moved original OxyContin to the ''Discontinued Drug Product List'' section of the Orange Book. On April 16, 2013, FDA approved a supplemental application for reformulated OxyContin, approving changes to the product labeling that describe certain abuse-deterrent properties of the reformulated product.

Several parties have submitted citizen petitions under 21 CFR 10.30, requesting that the Agency determine whether original OXYCONTIN (oxycodone hydrochloride) extended-release tablets were voluntarily withdrawn from sale for reasons other than safety or effectiveness.[1]

Based on the information available at this time, FDA has determined under § 314.161 that original OxyContin was

[1] Varam, Inc., Docket No. 2011–P–0473 (June 9, 2011) (10, 15, 20, 30, 40, 50, 80, and 160 mg); Sheppard, Mullin, Richter & Hampton LLP, Docket No. 2010–P–0540 (Oct. 8, 2010) (10, 15, 20, 30, 40, 60, and 80 mg); Lachman Consultant Services, Inc., Docket No. FDA–2010–P–0526) (Sept. 30, 2010) (10, 15, 20, 30, 40, 60, 80, and 160 mg). Lachman also submitted a petition in 2001 concerning just Purdue's 2001 withdrawal of the 160 mg strength. Docket No. FDA–2001–P–0473 (formerly Docket No. 2001P–0426) (Sept. 18, 2001).