

time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:*

December 10, 2007. The applicant claims June 26, 2008, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 10, 2007, which was 30 days after FDA receipt of the first IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 12, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for BREO ELLIPTA (NDA 204275) was initially submitted on July 12, 2012.

3. *The date the application was approved:* May 10, 2013. FDA has verified the applicant's claim that NDA 204275 was approved on May 10, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 981 days of patent term extension.

### III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–03551 Filed 2–19–16; 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; 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 April 22, 2016.

**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–2010–N–0117 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims.” 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 Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be

made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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:

- 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.

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

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
Total .....					30

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

Dated: February 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-03543 Filed 2-19-16; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Exclusive License: Production of Attenuated Respiratory Syncytial Virus Vaccines**

**AGENCY:** National Institutes of Health.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: (1) E-194-1999/0, Collins et al., “Production of Attenuated Respiratory Syncytial Virus Vaccines Involving Modification of M2 ORF2”, U.S. Provisional Patent Application Number 60/143,097, filed July 9, 1999, PCT Patent Application Number PCT/US2000/18534, filed July 7, 2000, U.S. Patent Application Number 09/611,829 (now U.S. Patent Number 6,713,066), and U.S. Patent Application Number 11/011,502 (now U.S. Patent Number 7,485,440), (2) E-135-2010/0, Collins et al., “Genetically Stable Live Attenuated Vaccine for Respiratory Syncytial Virus

(RSV) with an Attenuation and Temperature Sensitive Phenotype Conferred by an Amino Acid Deletion”, U.S. Provisional Patent Application Number 61/624,010, filed April 13, 2012, PCT Patent Application Number PCT/US2013/030836, filed March 13, 2013, United States Patent Application Number 14/394,226, filed October 13, 2014, European Patent Application Number 13712641.3, filed March 13, 2013, (3) E-216-2014/0, Collins et al., “Versions of Respiratory Syncytial Virus (RSV) Vaccine Candidate LID Delta M2-2 with Increased Attenuation”, U.S. Provisional Patent Application Number 62/266,199, filed December 11, 2015, (4) E-241-2014/0, Collins et al., “Improved RSV F Protein for Expression from a Heterologous Vector”, U.S. Provisional Patent Application Number 62/105,667, filed January 20, 2015, PCT Patent Application Number PCT/US2016/014154, filed January 20, 2016, and (5) E-037-2016/0, Collins et al., “Attenuated RSV Vaccine Strains in which the NS1 and/or NS2 Genes have been Shifted to Promoter-Distal Positions”, U.S. Provisional Patent Application Number 62/266,206, filed December 11, 2015, to Sanofi Pasteur, Inc., having a place of business in Swiftwater, Pennsylvania, U.S.A. The patent rights in this invention have been assigned to the United States of America.

**DATES:** Only written comments and/or application for a license which are received by the National Institute of Allergy and Infectious Diseases, Technology Transfer and Intellectual Property Office on or before March 8, 2016. will be considered.

**ADDRESSES:** Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Senior Technology Licensing Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, Rockville, MD 20852-9804, Tel: (301) 594-8730 or email: *ps193c@nih.gov*.

**SUPPLEMENTARY INFORMATION:** Respiratory syncytial virus (RSV) is the most important cause of viral acute lower respiratory infection (ALRI) in infants and children worldwide and is responsible for over 30 million new ALRI episodes worldwide and up to 199,000 deaths in children under five (5) years old. In the United States, the virus infects nearly all children at least once by the age of two (2) and is the most common cause of bronchiolitis and infant pneumonia, causing up to 125,000 hospitalizations of children each year. RSV disease burden is less understood in the developing world, but available data indicates that the virus causes a significant proportion of childhood ALRI in these parts of the world, particularly in the first months of life. The drug palivizumab (Synagis) can help prevent RSV disease in high risk infants, but it cannot treat or cure already-serious RSV infection. No vaccine exists today to prevent RSV due to an incomplete understanding of the body’s immune response to the virus, which has challenged and delayed RSV vaccine development efforts.

The methods and compositions of this invention provide a means for