information is missing. The ambulance provider/supplier or beneficiary can rectify the error(s) and resubmit the prior authorization request with appropriate documentation.

- Scenario 4: If an ambulance provider or supplier renders a service to a beneficiary and does not request prior authorization by the fourth round trip in a 30-day period, and the claim is submitted to the MAC for payment, then the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be for services that were not medically necessary or for which there was insufficient documentation, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The ambulance provider/supplier or the beneficiary, or both, can appeal the claim denial if they believe the denial was inappropriate.

++ If the claim is determined to be payable, it will be paid.

Under the model, we will work to limit any adverse impact on beneficiaries and to educate beneficiaries about the process. If a prior authorization request is non-affirmed, and the claim is still submitted by the ambulance provider/supplier, the claim will be denied, but beneficiaries will continue to have all applicable administrative appeal rights. We will also work to implement a process that will help identify alternate transportation resources for beneficiaries who receive non-affirmative decisions.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial ambulance provider/supplier cannot complete the total number of prior authorized transports (for example, the initial ambulance company closes or no longer services that area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required documentation in the submission. If multiple ambulance providers/suppliers are providing transports to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the ambulance provider/supplier indicated in the provisionally affirmed prior authorization request. Any ambulance provider/supplier submitting claims for repetitive, scheduled non-emergent ambulance transports for which no prior authorization request is submitted by the fourth round trip in a 30-day period will be subject to 100 percent prepayment medical review of those claims.

Additional information is available on the CMS website at http://go.cms.gov/PAAmbulance.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Regulatory Impact Statement

This document announces a 1-year extension of the Medicare Prior Authorization Model for Repetitive Scheduled Non-Emergent Ambulance Transport. Therefore, there are no regulatory impact implications associated with this notice.

Authority: Section 1115A of the Social Security Act.


Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2017–26759 Filed 12–8–17; 4:15 pm]
BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug

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 January 11, 2018.

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 0910–0001. 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, PRAS@ 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.

Application for FDA Approval To Market a New Drug

OMB Control Number 0910–0001—Extension

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the FD&C Act is effective with respect to such drug. The Agency has codified regulations regarding applications for FDA approval to market a new drug under 21 CFR part 314. This collection of information supports the regulatory requirements found in those regulations. The collection of information is necessary for FDA to make a scientific and technical determination whether the product is safe and effective for use, and is summarized as follows:

Section 314.50(a) requires that an application form (Form FDA 356h) be submitted that includes information about the applicant, the submission, and a checklist of enclosures.

Section 314.50(b) requires that an index be submitted with the archival copy of the application and that it reference certain sections of the application.

Section 314.50(c) requires that a summary of the application be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the new drug application (NDA) contain the following technical sections about the new drug: Chemistry, manufacturing,
and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; statistical; and pediatric use sections.

Section 314.50(e) requires the applicant to submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations be submitted with the archival copy.

Section 314.50(h) requires that patent information, as described under § 314.53, be submitted with the application. However, burden hours for § 314.50(h) are approved under OMB control numbers 0910–0513 (Patent Certification Forms FDA 3542 and FDA 3542a) and 0910–0786 (Abbreviated New Drug Applications (ANDAs) and 505(b)(2) Applications), and are therefore not included among the estimates found in table 1.

Section 314.50(i) requires that patent certification information be submitted in section 505(b)(2) applications for patents claiming the drug substance, drug product, or method of use.

Sections 314.50(j)(1)(i)(C) and 314.54(i) and (j) require that patent certification information be submitted for each patent listed in the “Approved Drug Products with Therapeutic Equivalence Evaluations” (the Orange Book) for a drug product approved in an NDA that is pharmaceutically equivalent to the proposed drug product in the original 505(b)(2) application and was submitted and was approved before the original 505(b)(2) application was submitted. Burden for these provisions is included under OMB control number 0910–0786.

Section 314.50(j) requires that applicants who request a period of marketing exclusivity submit certain information with the application.

Section 314.50(k) requires that the application contain a financial certification or disclosure statement or both.

Section 314.50(l) requires that an archival, review, and field copy of the application be submitted, including the content of labeling and all labeling and labels.

Section 314.52 requires that any notice of certification of invalidity, unenforceability, or non-infringement of a patent to each patent owner and the FDA holder be sent by a section 505(b)(2) applicant that relies on a listed drug. A 505(b)(2) applicant is required to amend the application at the time notice is provided to include a statement certifying that the required notice has been provided. A 505(b)(2) applicant also is required to amend the application to document receipt of the required notice. Burden hours for these provisions are included in OMB control number 0910–0786.

Section 314.53 sets forth the patent information requirements for applicants who submit applications or amendments to the application filed under section 505(b)(2) of the FD&C Act or supplements to the approved 505(b)(2) application. Burden hours for these collections are approved in OMB control number 0910–0786.

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the FD&C Act. The burden estimate for 505(b)(2) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (l).

Section 314.55 sets forth the assessment requirements for each application. The burden estimate for 505(b)(2) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (l).

Section 314.60 sets forth reporting requirements and patent certification requirements for sponsors who amend an unapproved 505(b)(2) application. Burden hours for the § 314.60(f) collections are approved under OMB control number 0910–0786.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (2) set forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A).

Section 314.80(i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. The burden hours for § 314.80(i) are approved under OMB control numbers 0910–0230 (Adverse Drug Experience Reporting) and 0910–0291 (MedWatch: FDA’s Medical Reporting Program), and therefore burden estimates are not included in table 1.

Section 314.81(b)(1) requires that NDA and ANDA field alert reports be submitted to FDA (Forms FDA 3331 and Form FDA 3331a).

Section 314.81(b)(2) requires that annual reports be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling be submitted to FDA (Form FDA 2253).

Section 314.81(b)(3)(ii) requires that sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. The information collection burden estimate for NDA waiver requests is included in table 1 under the estimates for each section that is in part 314, subpart B.

Section 314.93 sets forth requirements for submitting a suitability petition to request a change from a listed drug in accordance with § 10.20 (21 CFR 10.20) and § 10.30. The burden hours for § 314.93 are approved under OMB control number 0910–0191 (Administrative Practices and Procedures; Formal Evidentiary Public Hearing) and are not included in table 1.

Section 314.94(a) through (d) require that an ANDA contain the following information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; and patent certification.

Section 314.95 requires that any notice of certification of invalidity or non-infringement of a patent to each patent owner and the NDA holder be sent by ANDA applicants.

Section 314.96 sets forth requirements for amendments to an unapproved ANDA.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for certain changes to the application. Approval of burden hours for information collections for §§ 314.95 through 314.97 are covered under OMB control number 0910–0786.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements for ANDAs. The burden hours for § 314.98(a) are approved under OMB control numbers 0910–0230 and 0910–0291 and are not included in table 1 of this document.

Section 314.98(b) requires the submission of annual reports for ANDAs: Field alert reports (Form FDA 3331a), annual reports (Form FDA 2252), and
Section 314.99(a) requires that applicants comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with § 314.92 through 314.99. The information collection burden estimate for ANDA waiver requests is included in table 1 of this document under § 314.201 and approved under OMB control number 0910–0191, and therefore are not included in table 1.
§ 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.200(f) states that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. The burden hours for § 314.200(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.200(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact, which justifies a hearing. The burden hours for § 314.200(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. The burden hours for § 314.430 are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.420(g) states that a person who responds to a proposed order from FDA denying a request for a hearing provide sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact, which justifies a hearing. The burden hours for § 314.420(g) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.450 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. The burden hours for § 314.450 are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.420(f) states that an applicant may submit a petition for stay of action before requesting an order from a court for a stay of action pending review. The burden hours for § 314.420(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.530(f) requires that an applicant first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. The burden hours for § 314.530(f) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, are approved under OMB control number 0910–0191, and therefore are not included in table 1.

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We retain the currently approved burden estimate for the information collection associated with the provisions identified above. At the same time, we have added burden estimate associated with §314.103, although in an effort to reduce burden, we have issued associated guidance to assist respondents with the relevant information collection.

Dated: December 6, 2017.

Leslie Kux,
Associate Commissioner for Policy.

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1030]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 requirements for declaring major food allergens under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by February 12, 2018.

ADDRESS: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 12, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of February 12, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Submission of Comments
Submit comments electronically by following the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that any confidential information in 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 https://www.regulations.gov.

For written/paper comments submitted to the Dockets Management Staff, 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–2014–N–1030 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food Allergen Labeling and Reporting.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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 docket, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/