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.

Dated: November 16, 2017.

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, *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.

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(i)(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 NDA 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)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. The burden hours for § 314.81(b)(3)(iii) are approved under OMB control number 0910–0045 (Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution), and therefore are not included in table 1.

Section 314.90 sets forth requirements for 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 other postmarketing reports for ANDAs: Field alert reports (Form FDA 3331a), annual reports (Form FDA 2252), and

advertisements and promotional labeling (Form FDA 2253). (The information collection burden estimate for field alert reports is included in table 1 of this document under § 314.81(b)(1); the estimate for annual reports is included under § 314.81(b)(2); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors 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 the estimates for each section that is in part 314, subpart C.)

Section 314.101(a) states that if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.102 covers communications between FDA and applicants, including requests for meetings.

Section 314.103 covers specified dispute resolution. To assist respondents with certain aspects of this requirement, we have issued draft guidance entitled ''Requests for Reconsideration at the Division Level Under GDUFA [the Generic Drug User Fee Act]; Guidance for Industry.''

Section 314.107(c) requires notice to FDA by the first applicant to submit a substantially complete ANDA containing a certification that a relevant patent is invalid, unenforceable, or will not be infringed of the date of first commercial marketing. The burden estimate for § 314.107(c) is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (*l*).

Section 314.107(e) requires that an applicant submit a copy of the entry of the order or judgment to FDA within 10 working days of a final judgment. The burden estimate for § 314.107(e) applications is included in table 1 under the estimates for § 314.50(a) through (g) and (i) through (*l*) and is approved under OMB control number 0910–0786.

Section 314.107(f) requires that ANDA or section 505(b)(2) applicants notify FDA immediately of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner must also notify FDA of the filing of any legal action for patent infringement. If the patent owner or approved application holder who is an exclusive patent licensee waives its opportunity to file a legal action for patent infringement within the 45-day period, the patent owner or approved application holder may submit to FDA a waiver in the specified format. The burden estimate for § 314.107(f) is included in table 1 under the estimates for § 314.50 (a) through (g) and (i) through (*l*) and is approved under OMB control number 0910–0786.

Section 314.110(b)(3) states that, after receipt of an FDA complete response letter, an applicant must either: (1) Resubmit the application addressing all the deficiencies identified in the complete response letter; (2) withdraw the application; or (3) request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. The burden hours for § 314.110(b)(3) are included under parts 10 through 16 (21 CFR parts 10 through 16, OMB control number 0910–0191) hearing regulations, in accordance with § 314.201, and are not included in table 1.

Section 314.122(a) requires that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. The burden hours for § 314.122(a) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. The burden hours for § 314.122(d) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Sections 314.125 and 314.127 state that FDA may refuse to approve an NDA or an ANDA and will provide the applicant written notice of an opportunity for a hearing under § 314.200 along with the reason for refusal to approve the application, including lack of a patent certification or statement with respect to each listed patent for an approved drug product that is pharmaceutically equivalent to the drug product for which the original 505(b)(2) application is submitted and was approved before the original 505(b)(2) was submitted. The burden hours for §§ 314.125 and 314.127 (refuse to approve an ANDA) are included under parts 10 through 16 hearing regulations (in accordance with § 314.201) and approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. The burden hours for § 314.126(c) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Sections 314.150(a) and (b) and 314.151(a) and (b) set forth requirements for the withdrawal of approval of an NDA or ANDA and the applicant's opportunity for a hearing and submission of comments. The burden hours for § 314.151(a) and (b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, and approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. The burden hours for § 314.151(c) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.153(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. The burden hours for § 314.152(b) are included under parts 10 through 16 hearing regulations, in accordance with § 314.201, approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.161(b) and (e) sets forth the requirements for submitting a petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. The burden hours for § 314.161(b) and (e) are approved under OMB control number 0910–0191 and therefore are not included in table 1.

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. The burden hours for § 314.200(c), (d), and (e) 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(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 314.530(c) and (e) states that if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. The burden hours for § 314.530(c) and (e) 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 approved under OMB control number 0910–0191, and therefore are not included in table 1.

Section 314.550 requires an applicant with a new drug product being considered for accelerated approval to submit copies of all promotional materials to FDA during the preapproval and post-approval periods.

Section 314.610(b)(1) requires that applicants include a plan or approach to postmarketing study commitments in applications for approval of new drugs when human efficacy studies are not ethical or feasible, and provide status reports of postmarketing study commitments. The burden estimate for § 314.610(b)(1) is included in table 1 under the estimates for §§ 314.50(a) through (f), (k), and (*l*); and 314.81(b)(2)).

Section 314.610(b)(3) requires that applicants propose labeling to be provided to patient recipients in applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden estimate for § 314.610(b)(3) is included in table 1 under the estimates for § 314.50(e).

Section 314.630 requires that applicants provide postmarketing safety reporting for applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden hours for § 314.630 are approved under OMB control numbers 0910–0230 and 0910–0291, and therefore not included in table 1.

Section 314.640 requires that applicants provide promotional materials for applications for approval of new drugs when human efficacy studies are not ethical or feasible. The burden estimate for § 314.640 is included in table 1 under the estimates for § 314.81(b)(3)(i)).

In the **Federal Register** of May 26, 2017 (82 FR 24351), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the four information collection topics solicited in the notice. However, one comment was received regarding NDA submission criteria, and we have directed the comment to the appropriate Agency component for consideration.

Accordingly, we estimate the burden for this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR section/[FDA form No.]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
314.50 (a)–(g), (i)–(*l*)—Content and format of a 505(b)(1) or 505(b)(2) application.	378	1.33	503	1,921	966,263
314.52—Non-infringement of patents (NDAs)	7	3	21	16	336
314.95—Non-infringement of patents (ANDAs)	209	3	627	16	10,032
314.60—Amendments	564	9.96	5,618	80	449,440
314.65—Withdrawal of unapproved applications	27	71.63	1,934	2	3,868
314.70 and 314.71—Supplements and submissions	838	7.04	5,897	150	884,550
314.72—Change of ownership	142	2.04	289	2	578
314.81—Other postmarketing reports and 314.81(b)(1) [3331 and 3331a] field alert reports.	342	19.98	6,834	8	54,672
314.81(b)(2) [2252]—Annual reports	913	5.07	4,632	40	185,280
314.81(b)(3)(i) [2253]—Promotional labeling	529	81.66	43,198	2	86,396
314.94(a) and (d)—ANDA content	180.5	3.75	676.5	480	324,720
314.96(a)(1)—Amendments to unapproved ANDAs	514	26.66	13,647	80	1,091,760
314.97—Supplements to ANDAs	343	17.57	6,027	80	482,160
314.99(a)—Responsibilities of ANDA Applicants	265	7.04	1,867	2	3,734
314.101(a)—ANDA filing	1	1	1	0.50 (30 minutes)	0.50
314.103—Dispute resolution	75	2	150	5	750
314.420—Drug Master Files	500	2.06	1,028	61	62,708
314.550—Promotional material and subpart H applications	29	7.76	225	120	27,000

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]—Continued

21 CFR section/[FDA form No.]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					4,634,247.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] For most elements, ''Total Hours'' reflects estimated average burden as calculated by multiplying the number of respondents by the frequency of response and time necessary for the corresponding activity. In other instances, ''Total Hours'' is the average burden we attribute to all respondents, where individual respondent and time-frequency values have been estimated. All figures have been rounded to the nearest whole number.

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.

[FR Doc. 2017–26670 Filed 12–11–17; 8:45 am]

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.

ADDRESSES: 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.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow 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 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.*
- 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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/*