Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 021909	CHILDREN'S ALLEGRA HIVES.	Fexofenadine Hydrochloride.	30 mg	Tablet, Orally Disintegrating; Oral.	Sanofi-Aventis U.S., LLC.
NDA 022246	METOZOLV ODT	Metoclopramide Hydrochloride.	EQ 5 mg Base	Tablet, Orally Disintegrating; Oral.	Bausch Health US, LLC.
NDA 022291	PROMACTA	Eltrombopag Olamine	EQ 100 mg Acid	Tablet; Oral	Novartis.
NDA 022362	WELCHOL	Colesevelam Hydrochloride.	1.875 g/Packet	For Suspension; Oral	Daiichi Sankyo.
NDA 022396	DYLOJECT	Diclofenac Sodium	37.5 mg/mL (37.5 mg/mL)	Solution; Intravenous	Javelin Pharmaceuticals, Inc.
NDA 050368	ILOTYCIN	Erythromycin	0.5%	Ointment; Ophthalmic	Eli Lilly and Co.
NDA 050587	PRIMAXIN	Cilastatin Sodium; Imipenem.	EQ 250 mg Base/Vial; 250 mg/Vial.	Powder; Intravenous	Merck & Co., Inc.
NDA 201373	CHILDREN'S ALLEGRA HIVES.	Fexofenadine Hydrochloride.	30 mg/5 mL	Suspension; Oral	Sanofi-Aventis U.S., LLC.
NDA 208411	NARCAN	Naloxone Hydrochloride.	2 mg/Spray	Spray, Metered; Nasal.	Adapt Pharma.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23300 Filed 10–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3771]

Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' Forms FDA 3988, Transmittal of PMR/PMC Submissions for Drugs and Biologics, and FDA 3989, PMR/PMC Annual Status Report for Drugs and Biologics, are intended to facilitate submissions by drug and biological product application holders of complete and accurate information on postmarketing requirements (PMRs) and postmarketing commitments (PMCs) in a consistent format. Forms FDA 3988 and 3989 are published in draft form in Appendix A and B of the draft guidance for comment and are not intended to be used until the forms are finalized. The forms were developed, in part, in response to the recommendations from the Government Accountability Office (GAO) and the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) regarding the need for comparable information across annual status reports (ASRs) on PMRs and PMCs, to eliminate manual data entry, and to enhance FDA's ability to track PMRs and PMCs. These forms are expected to result in improved accuracy and timeliness of FDA's identification and review of those submissions containing information on PMRs and PMCs. This draft guidance covers the purpose of each form, when to use these forms, and how to submit these forms. The draft guidance also explains where applicants will be able to find the forms and instructions for their completion once the forms and instructions are finalized.

DATES: Submit either electronic or written comments on the draft guidance by December 21, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the collection of information set forth in this document by December 21, 2020.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 should include the Docket No. FDA–2018–N–3771 for ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' Received comments 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kathy Weil, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5367, Silver Spring, MD 20993–0002, 301–796–6054; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the proposed collection of information: 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:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' This draft guidance is intended for applicants that are required to report annually on the status of postmarketing studies and clinical trials for human drug and biological products under section 506B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356b) and its implementing regulations at §§ 314.81(b)(2)(vii) and 601.70 (21 CFR 314.81(b)(2)(vii) and 601.70). These forms are expected to result in improved accuracy and timeliness of FDA's identification and review of those submissions containing information on PMRs and PMCs. The purpose of the draft guidance is to explain why Forms FDA 3988 and FDA 3989 were created, describe the contents of the forms, and explain how to submit the forms electronically. The draft guidance also explains where applicants will be able to find the forms and instructions for their completion once the forms and instructions are finalized. Forms FDA 3988 and 3989 are published in draft form in Appendix A and B of the draft guidance for comment and are not intended to be used until the forms are finalized.

PMRs and PMCs are studies or clinical trials conducted by the applicant after FDA has approved a drug or biological product for marketing or licensing. These studies or clinical trials can be required under statute or regulation (PMRs) or agreed upon in writing by FDA and the applicant (PMCs). Section 130(a) of the Food and Drug Administration Modernization Act of 1997 amended the FD&C Act by adding section 506B of the FD&C Act (21 U.S.C. 356b). Under section 506B of the FD&C Act and its implementing regulations at §§ 314.81(b)(2)(vii) and 601.70, applicants must submit an ASR on PMRs and PMCs.[1] This report must address the progress of the PMR/PMC or the reasons for failing to conduct the requirement or commitment (section 506B(a) of the FD&C Act).

This draft guidance does not apply to postmarketing studies or clinical trials

[1] The FDA defines postmarketing studies or clinical trials for which annual status reports (ASRs) must be submitted under section 506B of the FD&C Act as those concerning a human drug or biological product's clinical safety, clinical efficacy, clinical pharmacology, or nonclinical toxicology that are either required by FDA (PMRs) or that are committed to, in writing, (PMCs) either at the time of approval of an application or a supplement or after approval of an application or supplement. See §§ 314.81(b)(2)(vii) and 601.70. FDA interprets section 506B of the FD&C Act to apply to postmarketing studies and clinical trials that are required under the Pediatric Research Equity Act (section 505B of the FD&C Act (21 U.S.C. 355c); §§ 314.55(b) and 601.27(b)), the animal efficacy rule (§§ 314.610(b)(1) and 601.91(b)(1)), accelerated approval (section 506(c)(2)(A) of the FD&C Act; §§ 314.510 and 601.41), and the Food and Drug Administration Amendments Act of 2007 (section 505(*o*)(3) of the FD&C Act (21 U.S.C. 355(*o*)(3)).

that are not subject to the reporting requirements of section 506B of the FD&C Act.[2] For example, the draft guidance does not apply to voluntary studies or clinical trials performed by an applicant or on an applicant's behalf that are neither required nor agreed upon in writing. This draft guidance also does not apply to PMCs related to chemistry, manufacturing, and controls or stability studies.

In a December 2015 report from the GAO entitled ''Drug Safety: FDA Expedites Many Applications, but Data for Postapproval Oversight Need Improvement,'' [3] the GAO recommended that FDA improve its data tracking to ensure the completeness, timeliness, and accuracy of information in its database on PMRs/PMCs. Additionally, in a July 2016 HHS OIG study entitled ''FDA is Issuing More Postmarketing Requirements, but Challenges with Oversight Persist,'' [4] the HHS OIG noted that FDA continued to have problems with its data management system and work processes, thereby hindering its ability to track PMRs. OIG recommended that FDA provide standardized forms for ASRs, ensure that the forms are complete, and require applicants to submit the forms electronically.

Based in part on the recommendations from GAO and HHS OIG, FDA created Forms FDA 3988 and FDA 3989 to improve its collection, identification, and use of information regarding PMRs and PMCs. Form FDA 3988 was developed to accompany an applicant's PMR/PMC-related submissions (*e.g.,* draft protocols, final protocols, interim reports, final reports, and PMR/PMC-related correspondence), except the ASR on PMRs and PMCs. Form FDA 3988 allows applicants to identify, in a standardized format, the type of PMR/PMC-related submission the applicant is making (*e.g.,* draft protocol) and the PMR or PMC to which the submission applies. Form FDA 3989 was developed so that applicants may provide ASR information on their PMRs and PMCs in a standardized format. The purpose of these forms is to assist applicants in providing clearly identified PMR/PMC-related submissions and in meeting their annual reporting requirements under section 506B of the FD&C Act and §§ 314.81(b)(2)(vii) and 601.70.

Use of Form FDA 3988 and 3989 is optional, but FDA encourages their use because the forms should facilitate FDA management and review of the applicant's submissions, as well as enhance the accuracy of data within FDA's electronic document archiving systems. FDA uses these archiving systems as a source from which to obtain data published annually in the **Federal Register** as required under section 506B(c) of the FD&C Act and to provide quarterly status updates of the PMR and PMC data on FDA's Postmarket Requirements and Commitments public web page (available at *https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm).*

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3521), 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 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.

Annual Status Report Information and Other Submissions for Postmarketing Requirements and Commitments: Using Forms FDA 3988 and FDA 3989

The draft guidance describes the purpose and content of Form FDA 3988, Transmittal of PMR/PMC Submissions for Drugs and Biologics, and Form FDA 3989, PMR/PMC Annual Status Report for Drugs and Biologics. These forms are intended for applicants that are required by statute or regulation, or that have agreed in writing, to conduct postmarketing studies or clinical trials concerning the clinical safety, clinical efficacy, clinical pharmacology, or nonclinical toxicology of a human drug or biological product as PMRs or PMCs. Applicants are required to submit ASRs on PMCs and PMRs under section 506B of the FD&C Act and its implementing regulations at §§ 314.81(b)(2)(vii) and 601.70, and this information collection is approved under OMB control numbers 0910–0001 and 0910–0338, respectively. For this reason, these existing control numbers will be updated to account for Forms FDA 3988 and FDA 3989.

Form FDA 3988 would include the following information:

- Applicant's name, Center that approved or licensed the application (Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research), application type (new drug application (NDA), biologics license application (BLA), abbreviated new drug application (ANDA), or investigational new drug application (IND)), and submission date.
- Six-digit application number and supplement number(s) as applicable.
- Drug or biologic product's established name (*e.g.,* proper name, U.S. Pharmacopeia/U.S. Adopted Name) and proprietary (trade) name(s), if any.
- Information for all PMRs and PMCs addressed in the submission, including type (PMR or PMC), PMR or PMC number, establishment date, and National Clinical Trial (NCT) number (if applicable).
- PMR/PMC submission type, including draft protocol, final protocol, interim report, final report, general correspondence, Pediatric Research

[2] Under § 314.81(b)(2)(viii), applicants submitting an annual report for human drug products must include a status report of postmarketing studies and clinical trials not included under § 314.81(b)(2)(vii) that are being performed by, or on behalf of, the applicant.

[3] Available at *https://www.gao.gov/products/GAO-16-192.*

[4] Available at *https://oig.hhs.gov/oei/reports/oei-01-14-00390.asp.*

Equity Act PMR deferral extension request, response to information request, request for revised milestones, and ''other,'' and a brief description of the submission's content or rationale.

- Name and title of the applicant's Responsible Official, and (as applicable) telephone and facsimile numbers, and email and mailing addresses.
- Signature of the applicant's Responsible Official or other Authorized Official, countersignature of the Authorized U.S. Agent, and date that the form is signed.

Form FDA 3989 would include the following information:

- Applicant's name, Center that approved or licensed the application, application type, and submission date.
- Six-digit application number and date of U.S. approval.
- Drug or biologic product's established name (*e.g.,* proper name, U.S. Pharmacopeia/U.S. Adopted Name) and proprietary (trade) name(s), if any.
- Alternate annual status report due date (*i.e.,* a date other than the approval date that FDA has allowed the applicant to use for annual reporting).
- Period covered by the report.
- PMR/PMC update for each ''Open'' PMR/PMC. Information includes PMR/PMC number, establishment date, supplement number as applicable, description, study or clinical trial title as applicable, current and expected enrollment of studies and clinical trials as applicable, study or clinical trial status, explanation of status, and milestone information (*e.g.,* milestone type, original date, revised date as applicable, the reason for the revision).
- Name and title of the applicant's Responsible Official, and (as applicable) telephone and facsimile numbers, and email and mailing addresses.
- Signature of the applicant's Responsible Official or other Authorized Official, countersignature of the Authorized U.S. Agent, and date that the form is signed.

Forms FDA 3988 and FDA 3989 are fillable forms supporting electronic signatures. Based on the number of applicants required by statute or regulation, or that have agreed in writing, to conduct postmarketing studies or clinical trials as PMRs or PMCs, and based on the number of PMR/PMC-related submissions that we currently receive annually, we estimate receiving approximately 1,908 Forms FDA 3988 and 636 Forms FDA 3989, annually, in accordance with the description in the draft guidance. We estimate that approximately 318 [5] applicants will submit these forms, and that each form, as described in the draft guidance, will take approximately 1 hour to prepare and electronically submit to FDA.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED REPORTING BURDEN [1] [2] [3]

§ 314.81	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3988	226	6	1,356	1	1,356
Form FDA 3989	226	2	452	1	452
Total					1,808

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours for Form FDA 3989 in this table includes and replaces the burden that applicants currently incur to complete the ASR on PMRs and PMCs that is currently submitted as part of the annual report under § 314.81(b)(2).
[3] Burden associated with OMB Control No. 0910–0001: *Applications for FDA Approval to Market a New Drug.*

TABLE 2—ESTIMATED REPORTING BURDEN [1] [2] [3]

§ 601.70	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Form FDA 3988	92	6	552	1	552
Form FDA 3989	92	2	184	1	184
Total					736

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours for Form FDA 3989 in this table includes and replaces the burden that applicants currently incur to complete the ASR on PMRs and PMCs that is currently submitted pursuant to § 601.70.
[3] Burden associated with OMB Control No. 0910–0338: *General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Form FDA 356h (21 CFR part 601).*

[5] This number is based on information from ''The Food and Drug Administration Report on the Performance of Drugs and Biologics Firms in Conducting Postmarketing Requirements and Commitments. Fiscal Year 2018'' available at *https://www.fda.gov/media/129657/download.*

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: October 13, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23290 Filed 10–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0781]

Agency Information Collection Activities; Proposed Collection; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) 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 record retention requirement of the soy protein/coronary heart disease health claim.

DATES: Submit either electronic or written comments on the collection of information by December 21, 2020.

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 December 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2020. 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–2011–N–0781 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim.'' 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, 240–420–7500.

- 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.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–420–7500.

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: Under the PRA (44 U.S.C. 3501–3521), 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