Part 111 (21 CFR part 111) establishes the minimum Current Good Manufacturing Practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) (21 CFR 111.75(a)(1)) establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. Under § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1) an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 (21 CFR 10.30)and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB control number 0910–0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

In the **Federal Register** of March 9, 2015 (80 FR 12491), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received, but was not responsive to the four collection of information topics solicited in the notice and, therefore, is not discussed in this document.

We estimate the annual burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; CGMP requirements for dietary supplements	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii)	1	1	1	8	8

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the last 3 years, we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Based on our experience with petition processes, we estimate it will take a requestor about 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition. Although we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, we believe that OMB approval of these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients.

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12398 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Pharmacy Compounding Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pharmacy Compounding Advisory Committee.

General Function of the Committee: To provide advice on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs.

Date and Time: The meeting will be held on June 17, 2015, from 8:30 a.m. to 5 p.m., and on June 18, 2015, from 8:30 a.m. to 11:30 a.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/*

AboutAdvisoryCommittees/ucm408555.htm.

Contact Person: Jayne E. Peterson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PCAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Background: Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

The Drug Quality and Security Act adds a new section, 503B, to the FD&C Act (21 U.S.C. 353b) that creates a new category of ''outsourcing facilities.'' Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registration with FDA as an outsourcing facility. If these conditions are satisfied, a drug product compounded for human use by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1), (2) section 505, and (3) section 582 (21 U.S.C. 360eee–1), but not section 501(a)(2)(B).

One of the conditions that must be satisfied to qualify for the exemptions under both sections 503A and 503B of the FD&C Act is that the drug that is compounded does not appear on a list published by the Secretary of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (''withdrawn or removed list'') (see sections 503A(b)(1)(C) and 503B(a)(4) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that a bulk drug substance (active pharmaceutical ingredient) used in a compounded drug must meet one of the following criteria: (1) Complies with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if an applicable monograph does not exist, is a component of a drug approved by the Secretary of Health and Human Services (the Secretary); or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list (''section 503A bulk drug substances list'') developed by the Secretary through regulations issued by the Secretary (see section 503A(b)(1)(A)(i) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the compounded drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (see section 503A(b)(3)(A) of the FD&C Act).

Another condition that must be satisfied to qualify for the exemptions in section 503B of the FD&C Act is that the compounded drug is not identified (directly or as part of a category of drugs) on a list published by the Secretary of drugs or categories of drugs that present demonstrable difficulties for compounding that are reasonably likely to lead to an adverse effect on the safety or effectiveness of the drug or category of drugs, taking into account the risks and benefits to patients, or the drug is compounded in accordance with all applicable conditions that are necessary to prevent the drug or category of drugs from presenting such demonstrable difficulties (see section 503B(a)(6)(A) and (B) of the FD&C Act).

FDA will discuss with the committee drugs proposed for inclusion on the withdrawn or removed list pursuant to sections 503A and 503B and on the section 503A bulk drug substances list. FDA will also discuss with the committee the criteria FDA proposes to use to evaluate candidates to be identified as difficult to compound pursuant to sections 503A and 503B.

Agenda: On June 17, 2015, during the morning session, the committee will receive updates on certain issues to follow up on discussions from the last meeting including the options for obtaining access to investigational new drugs and the processes FDA plans to use to add or remove drugs from the section 503A bulk drug substances list. During this session, the committee will also discuss revisions FDA is considering to the list of drug products that may not be compounded under the exemptions provided by the FD&C Act because the drug products have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective. The list of those drug products is currently codified at 21 CFR 216.24. FDA now is considering whether to amend the rule to add four more drugs to the list: Aprotinin, ondansetron hydrochloride, bromocriptine mesylate, and acetaminophen. As previously explained in the **Federal Register** of July 2, 2014 (79 FR 37687 at 37689 through 37690), the list may specify that a drug may not be compounded in any form, or, alternatively, may expressly exclude a particular formulation, indication, dosage form, or route of administration from an entry on the list because an approved drug containing the same active ingredient(s) has not been withdrawn or removed from the market. Moreover, a drug may be listed only with regard to certain formulations, indications, routes of administration, or dosage forms because it has been found to be unsafe or not effective in those particular formulations, indications, routes of administration, or dosage forms. FDA plans to seek the committee's advice concerning the inclusion of these drug products.

On June 17, 2015, during the afternoon session, the committee will discuss four bulk drug substances nominated for inclusion on the section 503A bulk drug substances list. FDA intends to discuss the following nominated bulk drug substances: Brilliant Blue G, tranilast, N-acetyl-D-glucosamine, and oxitriptan. The nominators of these substances will be invited to make a short presentation supporting the nomination. Other nominated substances will be discussed at future committee meetings.

During the morning session on June 18, 2015, the committee will discuss the criteria FDA is proposing to use to evaluate drug products or categories of

drug products for identification as demonstrably difficult to compound.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 9, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:15 a.m. and 3:45 p.m. to 4 p.m. on June 17, 2015, and between approximately 9:15 a.m. to 9:45 a.m. on June 18, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 4, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 8, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jayne E. Peterson at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 19, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–12512 Filed 5–21–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0639]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Requests for Inspection by an Accredited Person Under the Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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.*

SUPPLEMENTARY INFORMATION: On December 3, 2014, the Agency submitted a proposed collection of information entitled ''Requests for Inspection by an Accredited Person under the Inspection by Accredited Persons Program'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0569.

The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12399 Filed 5–21–15; 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; Submission for Office of Management and Budget Review; 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) 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 June 22, 2015.

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 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

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.*

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.

Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health

Claim—21 CFR 101.82(c)(2)(ii)(B)

OMB Control Number 0910–0428—Extension

Section 403(r)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.