in furtherance of FDA's goal of ensuring transparency regarding the qualifications of individuals selected to serve on FDA advisory committees, and in recognition that individual advisory committee members are best situated to evaluate the confidentiality of information contained in their CVs, including any considerations raised by their relationships and agreements with third parties, FDA will now be requiring that all CVs submitted as part of the nomination process for positions on FDA advisory committees be accompanied by a written consent form stating that, if the nominee is accepted as a member of an FDA advisory committee, the nominee consents to the publication of the nominee's CV to FDA's Web site, without FDA removing or redacting any information. The consent form requires that the nominee affirm that the CV does not include any confidential information, including information pertaining to third parties that the nominee is not permitted to disclose. A nominee will be required to submit a signed consent form as a part of the nomination package in order for the nomination to be considered complete.

All nominations for new advisory committee members will be required to be submitted through FDA's Web site at *http://accessdata.test.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* or any successor system, and the submission will be required to be accompanied by the consent form, on or after the date of OMB approval for this information collection.

In the **Federal Register** of February 6, 2017 (82 FR 9383), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the information collection and recommended no changes to the Agency's burden estimate. On our own initiative, however, we have revised the estimate provided in our 60 day notice to reflect an increase of 23.5 burden hours and 94 responses. While we believe our original burden estimate accurately reflects the time burden associated with providing the specific data elements, but we have increased the number of respondents to the collection to include Industry Representative members of FDA advisory committees.

We therefore estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 14; subpart E—members of advisory committees	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Advisory Committee Membership Nominations	583	1	583	0.25 (15 minutes)	145.75
Representative Member Submission of Updated Information	64	1	64	0.25 (15 minutes)	16.0
Total			647		161.75

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

Based on a review of data, we received 638 nominations for membership to FDA advisory committees in Fiscal Year (FY) 2011; we received 603 nominations in FY 2012; we received 622 in FY 2013; we received 545 in FY 2014; and we received 505 nominations in FY 2015. By averaging the number of nominations received annually over the past 5 years, we estimate there are approximately 583 respondents to the information collection. We estimate it takes respondents 15 minutes to complete an initial nomination, where accompanying documentation is already available or has been prepared in advance by respondents. Multiplying 15 minutes (0.25) by the number of respondents to the information collection (583) equals 145.75 annual burden hours.

We have also included a burden estimate for members who currently serve on FDA advisory committees who are not Special Government and Regular Government Employees and who must submit an updated CV and an executed/completed consent form annually. Currently there are 64 authorized positions for these Representative members, mostly Industry representatives. While some positions are vacant, we anticipate the positions will be filled during the year. The request for the updated CV and consent will be made through email communications by the Designated Federal Officer of the committee. We anticipate that the burden to the respondent will be the same as that for new nominations. We estimate each response will require 15 minutes (0.25) for a total of 16 annual hours.

Dated: May 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–10531 Filed 5–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA 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 information collection requirements related to the exceptions or alternatives to labeling requirements for products held by the Strategic National Stockpile (SNS).

DATES: Submit either electronic or written comments on the collection of information by July 24, 2017.

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 July 24, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 24, 2017. 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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0588 for ''Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile.'' 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile—OMB Control Number 0910–0614—Extension

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the Nation (see the PHS Act, 42 U.S.C. 247d–6b). This collection of medical products for use during national health emergencies, known as the SNS, is to ''provide for the emergency health security of the United States, including the emergency health security of children and other

vulnerable populations, in the event of a bioterrorist attack or other public health emergency.''

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

Under 21 CFR 201.26, 610.68, 801.128, and 809.11 (§§ 201.26, 610.68, 801.128, and 809.11), the appropriate FDA Center Director may grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the regulations may include conditions or safeguards so that the labeling for such products includes appropriate information necessary for the safe and effective use of the product given the product's anticipated circumstances of use. Any grant of an exception or alternative will only apply to the specified lots, batches, or other units of medical products in the request. The appropriate FDA Center Director may also grant an exception or alternative to the labeling provisions specified in the regulations on his or her own initiative.

Under §§ 201.26(b)(1)(i) (human drug products), 610.68(b)(1)(i) (biological products), 801.128(b)(1)(i) (medical devices), and 809.11(b)(1)(i) (in vitro diagnostic products for human use), an SNS official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores such products that are or will be included in the SNS may submit, with written concurrence from a SNS official, a written request for an exception or alternative to certain labeling requirements to the appropriate FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- Identify the specific labeling provisions under the regulations that are the subject of the request;
- Explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product given the anticipated circumstances of use of the product;
- Provide copies of the proposed labeling of the specified lots, batches, or other units of the affected product that will be subject to the exception or alternative; and
- Provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the new drug application, biologics license application, premarket approval application, or premarket notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in the regulations may be used to satisfy certain reporting obligations relating to changes to product applications under §§ 314.70, 601.12, 814.39 and 807.81 (21 CFR 314.70 (human drugs), 21 CFR 601.12 (biological products), 21 CFR 814.39 (medical devices subject to premarket approval), or 21 CFR 807.81 (medical devices subject to 510(k) clearance requirements)). The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910–0001, 0910–0338, 0910–0120, and 0910–0231, respectively. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute, or store affected SNS products. Based on data from fiscal years 2014 and 2015, FDA estimates an average of one request annually for an exception or alternative received by FDA. FDA estimates an average of 24 hours preparing each request. The average burden per response for each submission is based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the regulations, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations. FDA estimates 8 hours to develop and revise the labeling to make such changes. The average burden per response for each submission is based on the estimated time to develop and revise the labeling to make such changes.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	24	24
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i)	1	1	1	8	8
Total					32

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

Dated: May 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–10535 Filed 5–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases: Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: June 21, 2017.

Open: 8:30 a.m. to 1:00 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Closed: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Melinda Nelson, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Grants Management Branch, 45 Center Drive, Natcher Building, Room 5A49, Bethesda, MD 20892, (301) 594–3535, *mn23z@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: May 17, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–10458 Filed 5–22–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Complementary and Integrative Health Special Emphasis Panel; NIH-DoD–VA Pain Management Collaboratory—Coordinating Center (U24).

Date: June 23, 2017.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20817.

Contact Person: Viatcheslav A Soldatenkov, MD, Ph.D., Scientific Review Officer, Office of Scientific Review, Division of Extramural Activities, NCCIH/NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, *soldatenkovv@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: May 17, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–10454 Filed 5–22–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; U41 Genomic Resources.

Date: June 12, 2017.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, 5635 Fishers Lane, Conference Room 3146, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Keith McKenney, Ph.D., Scientific Review Officer, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, Bethesda, MD 20814, 301–594–4280, *mckenneyk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: May 17, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–10455 Filed 5–22–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as