6. User and nonuser perception data summary; and

7. Investigational plans for studies and surveillance of the tobacco product, including a summary of proposed study protocols containing the following information (as applicable):

a. Study objective(s);

b. Study hypotheses;

c. Study design;

d. Study population (inclusion/exclusion criteria, comparison group(s));

e. Human subject protection information, including Institutional Review Board information;

f. Primary and secondary endpoints (definition and success criteria);

g. Sample size calculation;

h. Data collection procedures;

i. Duration of follow up and baseline and follow up assessments, and

j. Data analysis plan(s).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. In the Agency's experience, reviewing such information is critical to achieving a productive meeting. If the information package was previously submitted in the meeting request, it should be revised, as applicable, so that the information reflects the most current and accurate information available.

In the **Federal Register** of September 12, 2018 (83 FR 46174), FDA published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received; however, none were PRA related.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and Sending Meeting Request Letters for Manufacturers, Importers, and Researchers	83	1	83	10	830
Meeting Information Packages					
Combining and Submitting Meeting Information Packages for Manufacturers, Importers, and Researchers	83	1	83	18	1,494
Total					2,324

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

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 83 preapplication meetings will be requested.

The hours per response for combining and sending meeting request letters are estimated at 10 hours each, and the total burden hours for meeting requests are expected to be 830 hours. Based on FDA's experience, the Agency expects it will take respondents this amount of time to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting.

FDA estimates that 83 respondents will compile meeting information packages and submit to FDA at 18 hours per response. Based on FDA's experience, the Agency expects that it will take respondents, collectively, 1,494 hours (83 respondents × 18 hours) to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 2,324 hours (830 hours to prepare and submit meeting requests and 1,494 hours to prepare and submit information packages).

Our estimated burden for the information collection reflects an overall increase of 16 respondents and 448 hours. We attribute this adjustment to an increase in the number of industry meetings as the premarket tobacco application compliance deadlines will come due in the next 3 years.

Dated: May 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–11225 Filed 5–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee, June 18, 2019 to June 19, 2019, which was published in the **Federal Register** on May 20, 2019, 84 FR 22866.

This notice is being amended to update location information to Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. The date and time will remain the same. This meeting is closed to the public.

Dated: May 23, 2019.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–11206 Filed 5–29–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel, which was published in the **Federal Register** on May 20, 2019, 84 FR 22870.

The meeting date, time and place remain the same. This notice is amended to update contact information—Dr. Kathy Salaita, Chief,