

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>—Continued

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
111.180; records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement.	240	1,163	279,120	1 .....	279,120
111.210; requirements for what the master manufacturing record must include.	240	1	240	2.5 .....	600
111.260; requirements for what the batch record must include .....	145	1,408	204,160	1 .....	204,160
111.325; records that quality control personnel must make and keep for laboratory operations.	120	1	120	15 .....	1,800
111.375; records of the written procedures established for manufacturing operations.	260	1	260	2 .....	520
111.430; records of the written procedures for packaging and labeling operations.	50	1	50	12.6 .....	630
111.475; records of product distribution and procedures for holding and distributing operations.	15,000	1	15,000	0.4 (24 minutes) .....	6,000
111.535; records for returned dietary supplements .....	110	4	440	13.5 .....	5,940
111.570; records regarding product complaints .....	240	600	144,000	0.5 (30 minutes) .....	72,000
<b>Total</b> .....					<b>929,140</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75; petition for exemption from 100 percent identity testing .....	1	1	1	8	8

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We have made no changes to our estimate of the information collection based on our most recent review. However, in consolidating burden from information collection previously accounted for under OMB control number 0910–0608, the information collection reflects an increase of 8 hours and one response annually.

Dated: November 26, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–26250 Filed 12–4–19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2018–N–3207]

**Request for Nominations of Voting Members on a Public Advisory Committee; National Mammography Quality Assurance Advisory Committee**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the National Mammography

Quality Assurance Advisory Committee in the Center for Devices and Radiological Health. Nominations will be accepted for upcoming vacancies effective with this notice.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

**DATES:** Nominations received on or before February 3, 2020, will be given first consideration for membership on the National Mammography Quality Assurance Advisory Committee. Nominations received after February 3, 2020, will be considered for nomination to the committee as later vacancies occur.

**ADDRESSES:** All nominations for membership should be submitted electronically by logging into the FDA Advisory Nomination Portal at <https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm> or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA’s website at [https://](https://www.fda.gov/AdvisoryCommittees/default.htm)

[www.fda.gov/AdvisoryCommittees/default.htm](https://www.fda.gov/AdvisoryCommittees/default.htm).

**FOR FURTHER INFORMATION CONTACT:** *Regarding all nomination questions for membership:* Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5210, Silver Spring, MD 20993, 301–796–7047, email: [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for voting members to fill upcoming vacancies on the National Mammography Quality Assurance Advisory Committee.

**I. General Description of the Committee Duties**

The National Mammography Quality Assurance Advisory Committee advises the Commissioner of Food and Drugs (the Commissioner) or designee on: (1) Developing appropriate quality standards and regulations for mammography facilities; (2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program; (3) developing regulations with respect to sanctions; (4) developing procedures for monitoring compliance with standards; (5) establishing a mechanism to investigate consumer complaints; (6) reporting new developments concerning breast imaging that should be

considered in the oversight of mammography facilities; (7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas; (8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and (9) determining the costs and benefits of compliance with these requirements.

## II. Criteria for Voting Members

The committee consists of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

## III. Nomination Procedures

Any interested person may nominate one or more qualified persons for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Nomination Portal (see **ADDRESSES**). Nominations must specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflict of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: December 2, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-26279 Filed 12-4-19; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-4656]

#### Interstitial Cystitis/Bladder Pain Syndrome: Establishing Effectiveness of Drugs for Treatment; Draft Guidance for Industry; Availability

**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 “Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment.” There is pharmaceutical and stakeholder interest in the development of new drugs for patients with IC/BPS. This draft guidance provides FDA’s recommendations for clinical trials intended to establish clinical effectiveness and safety for drugs intended to treat IC/BPS.

**DATES:** Submit either electronic or written comments on the draft guidance by February 3, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**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 must include the Docket No. FDA-2019-D-4656 for “Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS): Establishing Effectiveness of Drugs for Treatment.” 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the