

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—NOTIFICATIONS TO FDA ¹—Continued

| Respondent description | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Total | | | | | 150 |

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT ¹

| Respondent description | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|-------------------------------------|-----------------------|--------------------------------------|--------------------------|-------------------------------|-------------|
| Manufacturers and Repackagers | 120 | 30 | 3,600 | 0.20 (12 minutes) | 720 |
| Wholesale Distributors | 22 | 1,175 | 25,850 | 0.20 (12 minutes) | 5,170 |
| Dispensers | 8 | 2 | 16 | 0.20 (12 minutes) | 3.2 |
| Total | | | | | 5,893 |

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR CONSULTATION WITH FDA AND TERMINATION OF NOTIFICATION ¹

| Respondent description | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|-------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Manufacturers and Repackagers | 120 | 1 | 120 | 1 | 120 |
| Wholesale Distributors | 22 | 1 | 22 | 1 | 22 |
| Dispensers | 8 | 1 | 8 | 1 | 8 |
| Total | | | | | 150 |

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

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN FOR NOTIFICATIONS TO TRADING PARTNERS OF AN ILLEGITIMATE PRODUCT TERMINATION ¹

| Respondent description | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|-------------------------------------|-----------------------|--------------------------------------|--------------------------|-------------------------------|-------------|
| Manufacturers and Repackagers | 120 | 30 | 3,600 | 0.2 (12 minutes) | 720 |
| Wholesale Distributors | 22 | 1,175 | 25,850 | 0.2 (12 minutes) | 5,170 |
| Dispensers | 8 | 2 | 16 | 0.2 (12 minutes) | 3.2 |
| Total | | | | | 5,893 |

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

Cumulatively, the total estimated burden is 12,086 annual hours, which reflects a significant decrease. We base this adjustment on our experience with the information collection since its establishment and implementation.

Dated: August 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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 November 5, 2018, will be given first consideration for membership on the National Mammography Quality

Assurance Advisory Committee. Nominations received after November 5, 2018, 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: <http://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 <http://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. G616, Silver Spring, MD 20993, 301-796-7047, email: 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: August 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2000-D-0277]

Allergic Rhinitis: Developing Drug Products for Treatment; 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

guidance for industry entitled "Allergic Rhinitis: Developing Drug Products for Treatment." The purpose of this guidance is to assist sponsors in the development of drug products for the treatment of allergic rhinitis in children and adults. The guidance addresses issues of trial design, effectiveness, and safety for new products being developed for the treatment of seasonal allergic rhinitis (SAR) and perennial allergic rhinitis (PAR). This guidance incorporates the comments received for and finalizes the draft guidance of the same name issued on February 16, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on September 6, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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