

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Full SE 905(j)(1)(A)(i) and 910(a)	683	1	683	300	204,900
Full SE 905(j)(1)(A)(i) and 910(a) Bundled	456	1	456	90	41,040
Product Quantity Change SE Report	239	1	239	87	20,793
Product Quantity Change Bundled SE Report	192	1	192	62	11,904
Total					278,637

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

FDA's estimates are based on experience with SE Reports, initial updated deemed registration and listing data, interactions with the industry, and information related to other regulated products. The estimated number of SE Reports is expected to increase from an annual average of 979 to 1,570.

When groups of full or product quantity change SE Reports have identical content, they may be bundled; when a group of similar reports are bundled, the subsequent bundled reports are expected to take less time to prepare than the initial report.

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j)(1)(A)(i) and 910(a) of the FD&C Act (21 U.S.C. 387j(a)) for an SE application.

FDA estimates that 683 respondents will prepare and submit 683 section 905(j)(1)(A)(i) SE Reports each year. In addition, anyone submitting an SE Report is required to submit an environmental assessment (EA) under 21 CFR 25.40. The burden for environmental reports has been included in the burden per response for each type of SE report. Based on FDA's experience with EAs for currently regulated tobacco products, we expect industry to spend 80 hours to prepare an environmental assessment for a SE Report. Thus, FDA estimates that it will take a manufacturer approximately 300 hours per report to prepare an SE Report and the EA for a new tobacco product, which is a total of 204,900 hours.

In addition, we estimate receiving 456 Full SE Bundled Reports at 90 hours per submission for a total of 41,040 hours.

FDA estimates that it will receive 239 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this

report for a total of 20,793 hours. This includes time to prepare the environmental assessment, which FDA believes will take less time due to the typically more limited modification(s) included in a Product Quantity Change SE Report. We estimate receiving 192 Product Quantity Change Bundled SE Reports at approximately 62 hours per submission for a total of 11,904 hours, this number excludes the time for the initial SE Report which was previously account for.

Therefore, FDA estimates the burden for submission of SE information will be 278,637 hours. This is an increase of 106,759 hours from the currently approved burden. We attribute this increase to an increase in the number of SE Reports we expect related to Deemed products (e.g., based on the initial registration and listing information).

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-3179]

Request for Nominations on Public Advisory Panels of the Medical Devices Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organizations interested in participating in the selection of nonvoting industry representatives to serve on certain panels of the Medical Devices Advisory Committee (MDAC or Committee) in the Center for Devices and Radiological Health (CDRH) notify FDA in writing. FDA is also requesting nominations for nonvoting industry

representatives to serve on certain device panels of the MDAC in the CDRH. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for current and upcoming vacancies effective with this notice.

DATES: Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to FDA by October 9, 2018 (see sections I and II of this document for further details). Concurrently, nomination materials for prospective candidates should be sent to FDA by October 9, 2018.

ADDRESSES: All statements of interest from industry organizations interested in participating in the selection process of nonvoting industry representative nomination should be sent to Margaret Ames (see **FOR FURTHER INFORMATION CONTACT**). All nominations for nonvoting industry representatives should be submitted electronically by accessing the FDA Advisory Committee Membership Nomination Portal: <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 of an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

FOR FURTHER INFORMATION CONTACT: Margaret Ames, Division of Workforce Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5264, Silver Spring, MD 20993, 301-796-5960, Fax: 301-847-8505, email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency is requesting nominations for nonvoting industry representatives to the panels listed in the table in this document.

I. Medical Devices Advisory Committee

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (FD&C Act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel,

according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories; advises on any possible risks to health associated with the use of devices; advises on formulation of product development protocols; reviews premarket approval applications for medical devices; reviews guidelines and guidance documents; recommends exemption of certain devices from the application of portions of the FD&C Act; advises on the necessity to ban a device; and responds to requests from the Agency to review

and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Committee also provides recommendations to the Commissioner or designee on complexity categorization of in vitro diagnostics under the Clinical Laboratory Improvement Amendments of 1988.

Dental Products Panel (two representatives—one to represent the medical device industry, and one to represent the dental drug industry).	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational products for use in dentistry, endodontics, or bone physiology relative to the oral and maxillofacial area and makes appropriate recommendations to the Commissioner of Food and Drugs.
Immunology Devices Panel	Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational in vitro devices for use in clinical laboratory medicine including oncology, immunology, and allergy and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Qualifications

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, within 60 days after the receipt of the FDA letter, to serve as the nonvoting member to represent industry interests for a particular device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select the nonvoting member to represent industry interests.

IV. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Nomination must include a current, complete résumé or curriculum vitae for each nominee including current business address and telephone number, email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). Nominations must also specify the advisory panel for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the particular device panels listed in the table. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

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.

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–2014–D–0609]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

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