

II. 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 the committee. 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.

III. Application Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. Contact information, current curriculum vitae, and the name of the committee of interest should be sent to the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**) within 30 days of publication of this document (see **DATES**). FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (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: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0386]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 proposed extension of an existing collection of information pertaining to registration and product listing for owners and operators of domestic tobacco product establishments and listing of ingredients in tobacco products.

DATES: Submit either electronic or written comments on the collection of information by June 22, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

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.

Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products (OMB Control Number 0910-0650)—Extension

On June 22, 2009, the President signed the Tobacco Control Act (Pub. L. 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301) by, among other things, adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(b) of the FD&C Act (21 U.S.C. 387e(b)), as amended by the Tobacco Control Act, requires that every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products register with FDA the name, places of business, and all establishments owned or operated by that person. Every person must register by December 31 of each year. Section 905(c) of the FD&C Act requires that first-time persons engaging

in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. Section 905(d) states that persons required to register under section 905(b) or 905(c) of the FD&C Act shall register any additional establishment that they own or operate in any state which begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products. Section 905(h) of the FD&C Act addresses foreign establishment registration requirements, which will go into effect when regulations are promulgated by the Secretary. Section 905(i)(1) of the FD&C Act, as amended by the Tobacco Control Act, requires that all registrants shall, at the time of registration under any such subsection, file with FDA a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution, along with certain accompanying consumer information, such as all labeling and a representative sampling

of advertisements. Section 904(a)(1) of the FD&C Act (21 U.S.C. 387d(a)(1)), as amended by the Tobacco Control Act, requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand or by quantity in each brand and sub-brand. Since the Tobacco Control Act was enacted on June 22, 2009, the information required under section 904(a)(1) of the FD&C Act must be submitted to FDA by December 22, 2009, and include the ingredients added as of the date of submission. Section 904(c) of the FD&C Act also requires submission of information whenever additives, or the quantities of additives, are changed.

FDA issued guidance documents on both: (1) "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" and (2) "Listing of Ingredients in Tobacco Products" to assist persons making such submissions

to FDA under the Tobacco Control Act. While electronic submission of registration and product listing information and ingredient listing information are not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data management and collection. To that end, FDA designed electronic submission applications to streamline the data entry process for registration and product listing and for ingredient listing. These tools allow for importation of large quantities of structured data, attachment of files (e.g., in PDFs and certain media files), and automatic acknowledgement of FDA's receipt of submissions.

FDA also developed paper forms (Form FDA 3741—Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments, and Form FDA 3742—Listing of Ingredients in Tobacco Products) as an alternative submission tool. Both the electronic submission application and the paper forms can be accessed at <http://www.fda.gov/tobacco>. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours | Total operating and maintenance costs |
|--|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|---------------------------------------|
| Form FDA 3741: Registration and Product Listing for Owners and Operators of Domestic Establishments (Electronic and Paper Submission)/Section 905(b), 905(c), 905(d) 905(h), or 905(i) of the FD&C Act | 125 | 1.6 | 200 | 3.75 | 750 | \$0.98 |
| Form FDA 3742: Listing of Ingredients (Electronic and Paper Submissions)/Section 904(a)(1) or 904(c) of the FD&C Act | 125 | 1.6 | 200 | 3 | 600 | 0.98 |
| Obtaining a DUNS Number (10% of Total Respondents) | 8 | 1 | 8 | .5 (30 minutes) | 4 | |
| Total | | | | | 1,354 | 1.96 |

Since this collection of information was last approved by OMB on October 15, 2012, its burden has remained the same at 1,354 reporting hours. This burden estimate was determined as a result of FDA experience over the past 3 years in the regulation of tobacco products and is based on the actual number of establishment registration and product listings and product ingredient submissions received during this time period. FDA estimates that the submission of registration information as required by section 905 of the FD&C Act will remain at 3.75 hours per establishment and, based on the actual

number of registration information submitted in the past 3 years and its experience, the Agency estimates that approximately 200 registrations will be submitted from 125 tobacco product establishments annually, for a total of 750 reporting burden hours. FDA estimates that the submission of ingredient listing information as required by section 904 of the FD&C Act will remain at 3 hours per tobacco product and, based on the actual number of product ingredient listings submitted over the past 3 years and its experience, the Agency estimates that approximately 200 ingredient listings

will be submitted from 125 tobacco establishments, for a total of 600 reporting burden hours.

FDA also estimates that obtaining a Dun and Bradstreet (DUNS) number will take 0.5 hours, and that 8 respondents (1 percent (1.25) of establishments required to register under section 905 and 5 percent (6.25) of submitters required to list ingredients under section 904) will not already have a DUNS number. The total burden is estimated to be 4 hours. Total burden hours for this collection, therefore is 1,354 hours.

Dated: April 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0882]

Generic Drug User Fees; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on the Generic Drug User Fee Amendments of 2012 (GDUFA). The legislative authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue to collect generic drug user fees for future fiscal years. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization; we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the Generic Drug User Fee Act Program Performance Goals and Procedures (*i.e.*, the Commitment Letter), provide a period of 30 days after the public meeting to obtain written comments from the public, and publish the comments on FDA's Web site. FDA invites public comment on the GDUFA program and suggestions regarding the features FDA should propose for the next GDUFA program.

DATES: The public meeting will be held on June 15, 2015, from 9 a.m. to 5 p.m. The public meeting may be extended or may end early depending on the level of public participation.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security

information, refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT:

Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993, 240-402-7946, Connie.Wisner@fda.hhs.gov; or Kimberly Giordano, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993, 301-796-1071, Kimberly.Giordano@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act, which included GDUFA (Pub. L. 112-144, title III), was signed into law by the President. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. Designed to speed access to safe and effective generic drugs to the public, GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. GDUFA also requires that generic drug facilities around the world provide identification information annually to FDA.

Additional information concerning GDUFA, including the text of the law, the Commitment Letter, key **Federal Register** documents, GDUFA-related guidances, performance reports, and financial reports may be found on the FDA Web site at <http://www.fda.gov/gdufa>.

II. Purpose of Public Meeting

FDA is announcing a public meeting on GDUFA. The authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees to fund the human generic drug review process. Section 744(C)(d)(2) (21 U.S.C. 379j-43(d)(2)) of the FD&C Act requires that before FDA begins negotiations with the regulated industry on GDUFA reauthorization, we do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization, (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred to in the

Commitment Letter, (3) provide a period of 30 days after the public meeting to obtain written comments from the public, and (4) publish the comments on the FDA Web site. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA Web site will satisfy these requirements. The purpose of the public meeting is to receive public input on the reauthorization of GDUFA, including specific suggestions for changes to the goals referred to in the Commitment Letter. FDA is interested in responses to the following two general questions and welcomes any other relevant information the public would like to share:

- What is your assessment of the overall performance of the GDUFA program to date?
- What aspects of GDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

In general, the meeting format will include presentations by FDA, scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. The amount of time available for public testimony will be determined by the number of persons who register to present at the meeting. A draft agenda and other background information for the public meeting will be posted at <http://www.fda.gov/gdufa> by June 8, 2015.

III. Meeting Attendance and Participation

FDA is seeking participation (*i.e.*, attendance and oral presentations) at the public meeting by all interested parties, including but not limited to scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, the generic drug industry, and the general public. If you wish to attend the meeting, please email your registration information to GenericDrugPolicy@fda.hhs.gov by June 1, 2015. Your email should contain complete contact information for each attendee, including name, title, affiliation, address, email address, and telephone number. Registration is free and is on a first-come, first-served basis. Early registration is recommended because seating is limited. Registrants will receive confirmation once they have been accepted. If registration becomes full prior to the meeting, FDA will place a notice on <http://www.fda.gov/gdufa>. Onsite registration on the day of the