TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of interview	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Usability Testing Screener	2,028	1	2,028	0.083 (5 minutes)	168
Total					10,622

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

The number of respondents to be included in each new pretest may vary, depending on the nature of the material or message being tested and the target audience. Table 1 provides examples of the types of studies that may be administered and estimated burden levels during the 3-year period. Time to read, view, or listen to the message being tested is built into the ''Hours per Response'' figures.

The burden for this collection has decreased by 18,437 hours from 29,059 to 10,622. FDA attributes this decrease to assessing the planned studies for the next 3 years.

Dated: November 9, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24924 Filed 11–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0001]

Medical Gas Regulation; Public Workshops; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing two public workshops entitled ''Medical Gas Regulation: Workshop I'' and ''Medical Gas Regulation: Workshop II.'' The topic to be discussed is potential areas of Federal drug regulation that should be revised with respect to medical gases.

DATES: The first public workshop will be held on December 15, 2017, from 9 a.m. to 5 p.m. The second public workshop will be held on February 9, 2018, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the workshops may end early. FDA may announce additional public workshop dates in the future, if needed.

Submit either electronic or written comments on these public workshops by March 15, 2018, for Workshop I, and by May 10, 2018, for Workshop II. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information.

ADDRESSES: The public workshops will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Rm. 1503 B–C (sections B and C of the ''Great Room''), Silver Spring, MD 20993–0002. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security-check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments may not be considered. For timely consideration, we request that electronic comments on workshop topics be submitted before or within 90 days after each workshop (*i.e.,* comments should be submitted by or before March 15, 2018, for Workshop I, and May 10, 2018, for Workshop II). FDA will have one shared docket for all workshops. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before the relevant date.

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–2017–N–0001 for ''Medical Gas Regulation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2465, Fax: 301–847–8440, email: *MedgasPublicWorkshops@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On May 5, 2017, President Trump signed the Consolidated Appropriations Act, 2017 (Pub. L. 115–31). Section 756 of the Consolidated Appropriations Act, 2017 requires FDA to issue final regulations revising Federal drug regulations with respect to medical gases. These public workshops are being held as part of FDA's implementation of the requirements of section 756.

Since the 2012 enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), FDA has engaged in multiple activities related to medical gases, including rulemaking. For example, in 2016, FDA issued the final rule ''Medical Gas Containers and Closures: Current Good Manufacturing Practice Requirements'' (81 FR 81685, November 18, 2016). Other activities include FDA's June 2017 revised draft guidance for industry on current good manufacturing practice for medical gases,[1] updated guidance for FDA inspectors regarding medical gases (March 2015),[2] an extensive review of Federal drug regulations related to medical gases from 2012 to 2014 (a report on the review was submitted to Congress in 2015),[3] and implementation of FDASIA's requirements regarding certification of medical gases (to date, over 70 certifications have been granted).

FDA intends to engage in additional rulemaking in this area in accordance with section 756 of the Consolidated Appropriations Act, 2017. To conduct rulemaking as efficiently as possible, FDA intends to build on the information and stakeholder input received since FDASIA's enactment. As noted in more detail below, FDA invites comments from stakeholders on specific medical gas issues that could or should be addressed in regulation.

II. Topics for Discussion at the Public Workshops

We are holding these workshops to provide an opportunity for medical gas manufacturers and any other interested members of the public to provide input on potential areas of Federal drug regulation that should be revised with respect to medical gases.

We are asking stakeholders to comment on existing medical gas issues which, in their view, should be addressed by regulation change (rather than through other means, such as revisions to guidance or inspection practices). Commenters should include concrete and specific reasons that rulemaking is preferable to other options. Commenters' views regarding the prioritization of particular rulemaking proposals would also be helpful. If a stakeholder would like a comment to be discussed at a particular public workshop, it should be submitted with a discussion request by no later than 1 week before the date of the workshop. If a stakeholder would like a comment to be included in FDA's consideration of public comments presented and received for a particular workshop, it should be submitted no later than 90 days after the date of the workshop. As noted above, the *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of May 10, 2018. Late comments will not be considered.

During Workshop I (December 2017), FDA intends to discuss the anticipated scope of the medical gas rulemaking, as well as three regulations to which stakeholders have previously requested changes: 21 CFR part 201 (labeling generally and labeling for medical air specifically), 21 CFR part 207 (registration and listing), and 21 CFR parts 210 and 211 (current good manufacturing practice). Depending on the number of speakers and time available, we may also consider comments on additional regulations.

During Workshop II (February 2018), FDA intends to discuss 21 CFR part 314 (adverse event reporting) and the intersection of regulations for medical gases and regulations for medical devices and animal drugs. Depending on the number of speakers and time available, we may also consider comments on additional regulations and medical gas issues not currently addressed in regulation. FDA is considering whether to schedule one or more additional public workshops in 2018 to hear from stakeholders regarding any remaining topics.

III. Participating in the Public Workshops

Registration: The workshops are free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

If you need special accommodations because of a disability, please contact *MedgGasPublicWorkshops@fda.hhs.gov* (or see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of each workshop.

Requests for Oral Presentations: If you wish to a make an oral presentation, you must register by submitting your name, title, firm name, address, telephone, email address, and Fax number to *MedgasPublicWorkshops@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) by December 8, 2017, for Workshop I, or February 2, 2018, for Workshop II. Please also indicate the type of organization you represent (*e.g.,* industry, consumer organization) and a brief summary of your remarks (including the discussion topic(s) that you would like to address).

FDA will try to accommodate all persons who wish to make a presentation; however, the duration of each speaker's presentation may be limited by time constraints. FDA will notify registered presenters of their

[1] Available at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm070270.pdf.*

[2] Available at: *https://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePrograManual/UCM125417.pdf.*

[3] Available at: *https://www.fda.gov/downloads/regulatoryinformation/lawsenforcedbyfda/significantamendmentstothefdcact/fdasia/ucm453727.pdf.*

scheduled presentation times. Persons registered to speak should check in before the workshops and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. An agenda will be made available at least 3 days before each workshop at *https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm.* FDA may also post specific questions for consideration at the meeting Web page; these will be made available at least 3 days before each workshop at *https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm.*

Streaming Webcast and Video of the Public Workshops: These public workshops will be webcast; the URL will be posted at *https://www.fda.gov/Drugs/NewsEvents/ucm582091.htm* at least 1 day before each workshop. A video record of the public workshops will be available at the same Web site address for 1 year.

Dated: November 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–24918 Filed 11–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0878]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient

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 to allow 60 days for public comment in response to the notice. This notice solicits comments on the procedure by which a manufacturer or distributor of a new dietary ingredient or of a dietary supplement containing a new dietary ingredient is to submit to FDA information upon which it has based its conclusion that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

DATES: Submit either electronic or written comments on the collection of information by January 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2013–N–0878 for ''Premarket Notification for a New Dietary Ingredient.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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 electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD