Adjusted number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
27	2	8	432

60-day FRN number of respondents	Number of responses (per respondent)	Average burden hours (per response)	Total burden hours
45	2	16	1,440

Dated: January 22, 2020.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2020–02091 Filed 2–3–20; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5473]

Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' FDA is issuing this guidance to provide manufacturers, packers, distributors, and their representatives (firms) with information to consider when developing FDA-regulated promotional labeling and advertisements (promotional materials) for prescription reference and biosimilar products licensed under the Public Health Service Act (PHS Act). Although the guidance covers promotional issues involving both reference and biosimilar products, some questions and answers are focused on only biosimilar product promotional materials. The guidance does not discuss considerations unique to promotional materials for interchangeable biosimilars.

DATES: Submit either electronic or written comments on the draft guidance by April 6, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–5473 for ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pepinsky, Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3248, Silver Spring, MD 20993–0002, 301–796–1200, email *CDER–OPDP–RPM@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' The draft guidance addresses questions firms may have when developing FDA-regulated promotional materials for prescription reference products [1] licensed under section 351(a) of the PHS Act (42 U.S.C. 262(a)) and prescription biosimilar products [2] licensed under section 351(k) of the PHS Act.

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable [3] with an FDA-licensed reference product. Specifically, section 351(k) of the PHS Act outlines (among other things) the requirements for demonstrating biosimilarity and defines a biosimilar as a biological product that is highly similar to the reference product notwithstanding minor differences in clinically inactive components and for which there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, or potency. As the number of licensed biosimilar products increases, FDA expects an increase in promotion involving reference products and biosimilar products. FDA is providing this guidance to address questions firms may have when developing FDA-regulated promotional materials for their reference products or biosimilar products. The guidance discusses considerations for presenting data and information about reference or biosimilar products in these promotional materials to help ensure they are truthful and non-misleading as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA's implementing regulations.[4]

The draft guidance includes the following considerations for developing promotional materials for reference products and biosimilar products:

- Identifying reference products and biosimilar products;
- Presenting information from the studies conducted to support licensure of the reference product in biosimilar product promotional materials when the information is included in the FDA-approved labeling of both the reference and the biosimilar products;
- Presenting data or information from the studies conducted to support a demonstration of biosimilarity in biosimilar product promotional materials when the data or information is not included in the FDA-approved labeling for the biosimilar product;
- Presenting comparisons between a reference product and a biosimilar product; and
- Submitting promotional materials to FDA.

The guidance also provides examples to illustrate some of the considerations outlined in the guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference and Biosimilar Products—Questions and Answers.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 202.1 have been approved under OMB control number 0910–0686; the collections of information in the guidance for industry ''Medical Product Communications That Are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers'' have been approved under OMB control number 0910–0856; the collections of information in 21 CFR 601.12 related to submissions of labeling changes and of advertisements and promotional labeling have been approved under OMB control number 0910–0338; and the collection of information resulting from the submission of Form FDA 2253 has been approved under OMB control number 0910–0001.

III. Request for Comment on Other Issues for Consideration

FDA is interested in additional issues related to the promotion of biological products licensed under section 351(k) of the PHS Act and their reference products licensed under section 351(a) of the PHS Act. One area of interest focuses on considerations about what firms may want to convey in promotional materials regarding products licensed as interchangeable to a reference product. FDA is specifically seeking input on the following:

(1) What promotional considerations unique to interchangeable biosimilars exist, if any?

(2) What other considerations can help promotional materials convey truthful and non-misleading information about interchangeable

[1] The term *reference product* means the single biological product licensed under section 351(a) of the PHS Act against which a biological product is evaluated in an application submitted under section 351(k) of the PHS Act (42 U.S.C. 262(i)(4)).

[2] In the guidance, the terms *biosimilar* and *biosimilar product* refer to a product that FDA has determined to be biosimilar to the reference product (see section 351(i)(2) and (k)(2) of the PHS Act) (42 U.S.C. 262(i)(2) and (k)(2))).

[3] In the guidance, the terms *interchangeable biosimilar* and *interchangeable product* refer to a biosimilar product that FDA has determined to be interchangeable with the reference product (see section 351(i)(3) and (k)(4) of the PHS Act).

[4] See sections 201(n) and 502(a) and (n) of the FD&C Act (21 U.S.C. 321(n) and 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e)(5)).

products to various audiences (*e.g.,* patients, healthcare providers)?

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02100 Filed 2–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–6050]

Food and Drug Administration/Federal Trade Commission Workshop on a Competitive Marketplace for Biosimilars; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), in collaboration with the Federal Trade Commission (FTC), is announcing a public workshop on March 9, 2020, ''FDA/FTC Workshop on a Competitive Marketplace for Biosimilars.'' The purpose of the public workshop is to discuss FDA and FTC's collaborative efforts to support appropriate adoption of biosimilars, discourage false or misleading communications about biosimilars, and deter anticompetitive behaviors in the biologic product marketplace.

DATES: The public workshop will be held on March 9, 2020, from 9 a.m. to 5 p.m. Persons seeking to speak at the public workshop must register by February 24, 2020. Persons seeking to attend but not speak at the public workshop must register by March 4, 2020. Section III provides attendance and registration information. Electronic or written comments will be accepted until April 9, 2020.

ADDRESSES: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the 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 will not be considered. Electronic comments must be submitted on or before April 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end April 9, 2020. 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–2019–N–6050 for ''FDA/FTC Workshop on a Competitive Marketplace for Biosimilars.'' 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.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments and will share it with FTC. 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.govinfo.gov/content/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: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New