Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** Vol. 87, No. 207 pages 65068–65069 on October 27, 2022. No public comments were received during the 60-day FRN.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

The eight focus groups together will include no more than 64 total individuals representing three major activities of the NPRC: the QOL Grants Program; the PFSP; and the Promotional Activities, Outreach, and Collaboration program. The burden for their participation is estimated at 1.5 hours per participant, for a total of 96 hours.

A maximum of 180 PFSP mentors, 400 PFSP peers, and 300 people served by QOL subgrantee programs are expected to respond to the web-based survey, for a total of 880 respondents. The approximate burden for survey completion is 15 minutes for the peer mentor survey, and 10 minutes for the peer survey and QOL end-user survey per respondent. In addition, an estimated 5 minute non-response survey will be administered to the PFSP mentors and PFSP peers who did not respond to the web-based survey.

This results in a total survey burden estimate of 14,050 minutes (234.17 hours). The estimated survey completion burden includes time to review the instructions, read the questions, and complete responses.

Data collection form	Respondent type	Number of respondents	Responses per respondent	Hours per response	Annual burden hours *	Cost per hour	Annual burden cost
Focus group—Quality of Life organizational representatives.	Private sector—business, non-profit, or local government.	24	1	1.50	36	[1] $45.01	$1,620.36
Focus group—Peer Mentors.	Individual	16	1	1.50	24	[2] 28.01	672.24
Focus group—Peer Mentees.	Individual	16	1	1.50	24	[2] 28.01	672.24
Focus group—Regional Champions.	Individual	8	1	1.50	12	[2] 28.01	336.12
Survey—Peer Mentor	Individual	180	1	0.25	45	[2] 28.01	1,260.45
Survey—Peers	Individual	400	1	0.17	68	[2] 28.01	1,904.68
Survey—Quality of Life End-User.	Individual	300	1	0.17	51	[2] 28.01	1,428.51
Survey—Non-response follow-up (Peer Mentor).	Individual	85	1	0.08	6.8	[2] 28.01	190.47
Survey—Non-response follow-up (Peers).	Individual	230	1	0.08	18.4	[2] 28.01	515.38
Total		1,259		.23 (weighted mean)	285.2		8,600.45

* This is maximum number of hours for year one of data collection which is the largest year for data collection.

[1] Bureau of Labor Statistics, Mean hourly wage for Social and Community Service Managers, May 2021 National Occupational Employment and Wage Estimates by ownership, Local government, including schools and hospitals, *https://www.bls.gov/oes/current/999301.htm#21-0000.*

[2] Bureau of Labor Statistics, Mean hourly wage for All Occupations, May 2021 National Occupational Employment and Wage Estimates, United States, *https://www.bls.gov/oes/current/oes_nat.htm#00-0000.*

** Annual burden hours were calculated from total minutes for each activity divided by sixty.*

Dated: February 17, 2023.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2023–03740 Filed 2–22–23; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0363]

Patient-Focused Drug Development for Long COVID; 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, the Agency, or we) is announcing the following public meeting entitled ''Patient-Focused Drug Development for Long COVID.'' The purpose of the public meeting is to allow FDA to obtain patient perspectives on the impact of Long COVID on daily life, patient views on treatment approaches, and decision factors considered when selecting a treatment.

DATES: The public meeting will be held virtually on April 25, 2023, from 10 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by June 26, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be hosted via a live webcast.

Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 26, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–0363 for ''Patient-Focused Drug Development for Long COVID; Public Meeting; Request for Comments.'' 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, 240–402–7500.

- 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.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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Shannon Sparklin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–9208, *PatientFocused@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This meeting will provide FDA with the opportunity to hear directly from patients and patient representatives about their experiences with Long COVID, including how Long COVID affects their daily life, the symptoms that matter most to them, their current approaches to treating Long COVID, and what they consider when determining whether or not to participate in a clinical trial. Long COVID, also known as post-COVID syndrome, post-acute sequalae of severe acute respiratory syndrome 2 coronavirus (SARS–CoV–2), long-haul COVID, or post-acute COVID–19 syndrome, is defined as persistence of COVID–19 symptoms 4 weeks beyond SARS–CoV–2 infection. Literature has reported two categories of Long COVID known as subacute or ongoing COVID–19 symptoms (4–12 weeks of persistent symptoms post-infection), and chronic or post-COVID syndrome (12 weeks or more of persistent symptoms post-infection). SARS–CoV–2 may cause cell damage to multiple organs in an infected person. The most commonly reported symptoms include fatigue, brain fog, pain, palpitations, shortness of breath, cough, insomnia, anxiety, depression, constipation, and nausea. Since Long COVID was recently recognized, there is currently no standardized framework for diagnosis and treatment. While no medicines have been approved to treat Long COVID, symptoms may be treated with medication, exercise, diet modification, and meditation. FDA is interested in adult and pediatric patients' perspectives on the following topics: (1) health effects and daily impacts; (2) current approaches to treatment; and (3) clinical trial participation.

For each topic, a brief discussion by a patient panel will begin the dialogue. This discussion will be followed by a facilitated discussion where FDA will invite patients and patient representatives from the viewing audience to provide comments by calling into the meeting via phone, or by submitting through the meeting platform live comments which may be read during the meeting by the meeting facilitator.

In addition to input generated through this public meeting, FDA is interested in receiving patient and patient representative input through written comments, which can be submitted to the public docket (see **ADDRESSES**). FDA's questions will be available on the meeting website and as part of the information provided in the public docket. When submitting comments, if you are commenting on behalf of a patient, please indicate that you are doing so, and answer the questions as much as possible from the patient's perspective.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at: *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-long-covid-04252023.*

II. Topics for Discussion at the Public Meeting

On April 25, 2023, FDA is conducting a public meeting on Patient-Focused Drug Development for Long COVID. FDA is interested in obtaining patient perspectives on the impact of Long COVID on daily life and patient views on treatment approaches, as well as clinical trial participation.

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://www.surveymonkey.com/r/LongCOVIDPFDD.* Persons without access to the internet can call 301–796–9208 to register.

If you need special accommodations due to a disability, please contact Shannon Sparklin (see **FOR FURTHER INFORMATION CONTACT**) no later than April 18, 2023.

Panelist Selection: Patients or patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients or patient representatives also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by April 4, 2023. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the

duration of comments may be limited by time constraints.

Streaming Webcast of the Public Meeting: This public meeting will be streamed via a webcast in both English and Spanish languages. Please register for the webcast by visiting *https://www.surveymonkey.com/r/LongCOVIDPFDD.*

The English-language webcast can be accessed via: *https://fda.yorkcast.com/webcast/Play/4eba453a2412474e98fff1fabcc63ac51d.* The Spanish-language webcast can be accessed via: *https://fda.yorkcast.com/webcast/Play/0385884d5655420fabd3a55a237926691d.* Simply click on the link and hit the ''play'' button and it will start. A test signal will be playing 30 minutes prior to the event, so you can click on the link at any point during that time to start. You will hear music playing during the test period and then the event will begin at 10 a.m. ET. If you would like to check your system now, you can click on the link and the page will open with a ''waiting'' statement showing.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible on the meeting website at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-long-covid-04252023.*

Dated: February 16, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03714 Filed 2–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0451]

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry entitled ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry.'' The draft guidance, when finalized, will provide industry with our view on the naming of plant-based food products that are marketed and sold as alternatives to milk (plant-based milk alternatives) and our recommendations on the use of voluntary nutrient statements. Industry's use of these recommendations for labeling plant-based milk alternatives will provide consumers with additional nutrition information to help them understand certain nutritional differences between these products and milk and make informed dietary choices. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by April 24, 2023 to ensure that FDA considers your comment on the draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by April 24, 2023.

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–2023–D–0451 for ''Labeling of Plant-based Milk Alternatives and Voluntary Nutrient Statements: Guidance for Industry; Agency Information Collection Activities; Proposed Collection; Comment Request.'' 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, 240–402–7500.

- 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.'' We will review this copy, including the claimed confidential information, in our 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.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, 240–402–7500.