Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that JOENJA (leniolisib), approved March 24, 2023, and manufactured by Pharming Technologies B.V., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that JOENJA (leniolisib), manufactured by Pharming Technologies B.V., meets the criteria for a priority review voucher.

JOENJA (leniolisib) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age or older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about JOENJA (leniolisib), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: April 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08518 Filed 4–21–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1259]

Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we), in cosponsorship with the Duke-Margolis Center for Health Policy, is announcing a public workshop entitled ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches.'' This workshop will address innovative manufacturing technologies for drug and biological products and will include a discussion of potential best practices, case studies from previous submissions, potential barriers to adoption, corresponding regulatory strategies, and the Advanced Manufacturing Technologies Designation Program.

DATES: The public workshop will be held on June 8, 2023, from 9 a.m. to 4:30 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by July 8, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the National Press Club, 529 14th Street NW, Washington, DC 20045.

You may submit comments as follows. 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 on July 8, 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–1259 for ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing Approaches.'' 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: Luke Durocher, Duke-Margolis Center for Health Policy, 1201 Pennsylvania Ave., Suite 500, Washington, DC 20004, 202–621–2800, *margolisevents@duke.edu.*

SUPPLEMENTARY INFORMATION:

I. Background

There is significant interest in the use, implementation, and advancement of innovative drug manufacturing approaches and technologies. In accordance with commitments described in the Prescription Drug User Fee Act (PDUFA) VII commitment letter ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027,'' [1] FDA agreed to conduct a public workshop by the end of fiscal year 2023 on the use of innovative manufacturing technologies for products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER).

Additionally, section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. 356l), as added by section 3213 of the Food and Drug Omnibus Reform Act of 2022 (FDORA), authorizes the Advanced Manufacturing Technologies Designation Program and requires FDA to publish a **Federal Register** notice announcing a public meeting to solicit industry and public feedback regarding this program.

FDA is holding a public workshop entitled ''Advancing the Utilization and Supporting the Implementation of Innovative Manufacturing'' to fulfill both the PDUFA VII commitment and the FD&C Act requirement described above. The purpose of the public workshop is to discuss potential best practices for drug applications that include innovative manufacturing technologies, sponsor-presented case studies from previous submissions involving innovative technology, potential barriers to the adoption of innovative manufacturing technologies, corresponding regulatory strategies, ways in which FDA will support the use of innovative manufacturing technologies and approaches for drug and biological products, and the Advanced Manufacturing Technologies Designation Program.

II. Topics for Discussion at the Public Workshop

The public workshop will include the following topics for discussion:

- Best practices and lessons learned from the CDER Emerging Technology Team and the CBER Advanced Technology Team programs from both industry and regulatory perspectives.
- Case studies from previous innovative technology submissions presented by industry sponsors.
- Potential barriers (*e.g.,* technical, regulatory) to the adoption of innovative manufacturing technologies.
- Regulatory strategies for the adoption of innovative manufacturing technologies, including submission strategies for the implementation of certain innovative technologies across multiple commercial products or multiple manufacturing sites.
- Science- and risk-based approaches for developing and accessing innovative technologies across platform products and sites to streamline adoption.
- Input and recommendations from stakeholders regarding initiation and implementation of the Advanced Manufacturing Technologies Designation Program, including the process and information needed to request a designation, the evaluation of designation requests, and the review of applications that involve use of designated advanced manufacturing technologies.[2]

III. Participating in the Public Workshop

Registration: Persons interested in attending this public workshop must register online at *https://duke.is/8zckq* by 9 a.m. Eastern Time, June 8, 2023. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by 9 a.m. Eastern Time, June 8, 2023. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Luke Durocher, Duke-Margolis Center for Health Policy, 202–621–2800, *margolisevents@duke.edu,* no later than 5 p.m. Eastern Time, May 25, 2023.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast. Refer to registration information online at *https://duke.is/8zckq.*

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff.

Dated: April 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08545 Filed 4–21–23; 8:45 am]

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[1] See section I.N.5, ''Advancing Utilization and Implementation of Innovative Manufacturing'' at *https://www.fda.gov/media/151712/download.*

[2] In the context of this program, *application* refers to an application submitted under section 505 of the FD&C Act (21 U.S.C. 355), or section 351 of the Public Health Service Act (42 U.S.C. 262).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0624]

Food Labeling in Online Grocery Shopping; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting information to help empower consumers with accurate, informative, and accessible food labeling. The purpose of this request is to obtain current information on the content, format, and accuracy of food label information that is presented to consumers through online grocery