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]

BILLING CODE 4164–01–P

[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

shopping platforms. We intend to use the information submitted in response to this notice to help improve consumer access to consistent and accurate nutrition, ingredient, and allergen information for packaged foods sold through e-commerce.

DATES: Either electronic or written comments on the notice must be submitted by July 24, 2023.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 24, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 24, 2023. 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–2023–N–0624 for ''Food Labeling in Online Grocery Shopping; Request for Information.'' 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.

FOR FURTHER INFORMATION CONTACT: Pedro A. Cruz, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371 or Carrol Bascus, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA seeks to improve dietary patterns in the United States to help reduce the burden of diet-related chronic diseases and advance health equity. We are committed to accomplishing this, in part, by empowering consumers with accurate, informative, and accessible food labeling to help them in choosing healthier diets.

For purposes of this document, ''e-commerce'' refers to commercial transactions conducted on the internet. The Coronavirus Disease 2019 (COVID–19) pandemic greatly increased the use of e-commerce in the United States, including online grocery food shopping, which is the focus of this request for information (RFI). In 2019, consumers in the United States spent $62.2 billion on online grocery sales (Ref. 1). In 2020, online grocery sales grew 54 percent, reaching $95.8 billion, and accounted for 7.4 percent of all grocery sales (Ref. 1). Between 2019 and 2020, consumer use of online platforms to purchase at least some of their groceries rose from 19 percent to 79 percent, and this number is expected to grow (Ref. 3). Online grocery orders are expected to make up 21.5 percent of all U.S. grocery sales in 2023 (Ref. 3).

Online grocery shopping could change consumer behavior for the long-term, given the shift in how people are purchasing groceries. The increase in online grocery shopping is an opportunity to ensure consumers are able to find and view label information that will help them make more informed and healthier food choices. In this document, the term ''online grocery'' refers to foods ordered through grocery retailer (*e.g.,* supermarket) websites, directly from the manufacturer's websites, and third-party online grocery providers (*e.g.,* a grocery fulfillment service that offers food products from various grocery retailers). It does not include ready-to-eat meals (*e.g.,* salad or hot food bar) that are ordered online from grocery providers for pick-up or delivery.

We are interested in the nutrition (*e.g.,* Nutrition Facts label), ingredient, and major food allergens label information that is available to consumers through online grocery shopping platforms. We are also seeking feedback about consumer experiences in

viewing food labeling information when grocery shopping online. In particular, we would like data on how consumers use food label information and the extent to which different consumer groups (*e.g.,* racial and ethnic minority groups, those living in rural communities, those with lower socioeconomic status, and persons with disabilities) access and use the information when shopping for groceries online.

II. Regulatory Framework for Food Labeling Requirements

FDA is responsible for assuring that foods sold in the United States are safe, wholesome, and properly labeled. FDA is responsible for implementing and enforcing the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 *et seq.*), the Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), and the Public Health Service Act (42 U.S.C. 201 *et seq.*). In carrying out our responsibilities under these laws, we ensure that food is safe, not adulterated, and not misbranded.

The Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) amended the FD&C Act to require most foods to bear nutrition labeling and to require food labels that bear nutrient content claims and certain health messages to comply with specific requirements (21 U.S.C. 343(q) and (r)). In addition, the 2016 Nutrition Facts Label final rule (81 FR 33741, May 27, 2016) updated the nutrition labeling requirements for packaged foods to reflect new scientific information and dietary recommendations.

The Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108–282) amended the FD&C Act to require that the label of a food that contains an ingredient that is or contains protein from a ''major food allergen'' declare the presence of the allergen in a manner described by the law (section 403(w) of the FD&C Act) 21 U.S.C. 343(w)). The Food Allergy Safety, Treatment, Education, and Research Act of 2021 (Pub. L. 117–11) amended the food allergen labeling requirements to add sesame to the definition of major food allergens.

FDA's food labeling regulations are found in Title 21 of the Code of Federal Regulations, part 101 (21 CFR part 101) and include requirements for nutrition information (§ 101.9), ingredient information (§ 101.4), statement of identity (§ 101.3), net quantity of contents (§ 101.7), and name and place of business (§ 101.5). The major food allergen labeling requirements are in section 403(w) of the FD&C Act.

III. Food Labeling and Online Grocery Shopping

FDA addressed the issue of online labeling of food products in a 2007 ''Dear Manufacturer'' letter. At that time, for consistency and to avoid consumer confusion, FDA recommended that the nutrition information presented online be similar to FDA's Nutrition Facts label requirements under § 101.9.[1] FDA maintained that, in some circumstances, information disseminated online by, or on behalf of, a regulated company met the definition of labeling in section 201(m) of the FD&C Act (21 U.S.C. 321(m)) and therefore is subject to the requirements of the FD&C Act. We recommended that, if manufacturers and distributors made claims or provided label information on their food products online, they ensure that the claims and other information is consistent with FDA's current laws and regulations (Ref. 2).

The primary purpose of food labeling is to provide consumers with information to make informed decisions about the food they are purchasing, to make safe choices, and to maintain healthy dietary practices. For this to be possible, consumers need accurate, informative, and accessible food labeling when shopping for groceries online.

We are aware that many grocery retailers, manufacturers, and third-party online grocery providers present some label information online, such as nutrition and ingredient information. However, there may be inconsistencies in how and where this information is being displayed between the different types of online platforms (*e.g.,* website, mobile application, etc.) and online grocery businesses (Ref. 3). For example, the Nutrition Facts label and ingredient information may not be consistently available for the same food packaged and sold through the different online grocery providers (Ref. 4). In some cases, there may be differences between the label on the food package and the information that is being made available online. This may include inconsistent nutrient values and differences in the format of the nutrition information presented online compared to the nutrition information that is declared on the package label.

In October 2021, FDA hosted the ''New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers'' (Summit). Part of the Summit was designed to help us learn more about labeling of food products offered for sale through e-commerce. One session focused on food labeling. The session specifically addressed the nutrition, ingredient, and allergen information that is displayed through online grocery shopping platforms. We also established a public docket for the Summit and received limited comments that discussed food labeling issues associated with grocery foods sold through e-commerce. To ensure we have current data and information to inform our work to empower consumers with consistent and accurate nutrition, ingredient, and allergen information when grocery shopping online, we are providing additional opportunity for comment through this RFI. To inform next steps, we will consider comments from the Summit as well as data and information submitted in response to this RFI.

IV. Request for Information

We request information on whether and how online grocery retailers, food manufacturers, and third-party online grocery providers are displaying nutrition, ingredient, and allergen information through online grocery shopping platforms. When responding, please identify the question by its number (such as 1.1) so that we can associate your response with a specific question. Specifically, we request data and information regarding:

1. Food Labeling Information Provided Through Online Grocery Shopping

1.1 The mandatory label requirements on most packaged foods include, in part, nutrition information (*e.g.,* Nutrition Facts label), ingredient information, and major food allergens information (when applicable). What mandatory label information is currently available through online grocery shopping platforms? How consistently is mandatory label information presented across online grocery shopping platforms? Please provide any data and evidence to support your response.

1.2 How is nutrition, ingredient, and major food allergens information presented through online grocery shopping platforms? For example, where is the information available on the web page in relation to the product? Please provide any data and evidence to support your response.

1.3 When provided, is the nutrition, ingredient, and major food allergens

[1] We consistently maintain that online labeling cannot be used in place of labeling that is required on the actual package. The regulations require all food in packaged form to be fully labeled on the package, regardless of how the product is sold (internet vs. retail store).

information in the same format as on the packaged product (*e.g.,* Nutrition Facts label format)? If pictures of the product are used, how does the manufacturer, retailer, or third-party online grocery provider ensure the information in the picture is consistent with the package label, readable, and accessible on all devices (*e.g.,* laptops, smartphones etc.)? Please provide any data and evidence to support your response.

2. Industry Considerations and Logistics of Food Labeling in Online Grocery Shopping

2.1 Grocery foods may be sold in various ways through e-commerce, (*e.g.,* directly from the manufacturer, a retailer, or through a third-party online grocery provider). How do manufacturers, grocery retailers, and third-party online grocery providers decide what label information to display for grocery foods sold through online platforms (websites, mobile applications, etc.)? Please provide any data and evidence to support your response.

2.2 What challenges and limitations do online grocery retailers, manufacturers and third-party online grocery providers encounter when seeking to display food labeling information on their respective platforms? Please provide any data and evidence to support your response. Also, what, if any, are the labeling challenges for international websites selling groceries online?

2.3 How do manufacturers, retailers, and third-party online grocery providers ensure that information online is consistent with the actual product package and that the information is accurate and up to date? Please provide any data and evidence to support your response.

2.4 How do online retailers and third-party online grocery providers address manufacturer reformulations that may alter a product's nutrition, ingredient, or major food allergens information? If there is a change or error detected, how do online grocery shopping platforms collect the information and update the website (*e.g.,* is there a customer feedback loop or internal quality assurance process to detect and correct online labeling errors)? Please provide any data and evidence to support your response.

2.5 What measures are online grocery shopping platforms taking to ensure that consumers can access accurate nutrition, ingredient, and major food allergens information when purchasing groceries online? Have online grocery shopping platforms identified or capitalized on opportunities to leverage online platforms (*e.g.,* interactive labeling) to improve consumer engagement with and accessibility to food labeling information? Please provide any data and evidence to support your response.

2.6 How are online grocery shopping platforms seeking to ensure online access to labeling information is equitable for consumers? Do current online labeling presentations present barriers to accessing labeling information for certain consumers? Please provide any data and evidence to support your response.

3. Consumer Use of Food Label Information in Online Grocery Shopping

3.1 What food label information do consumers expect to see when shopping for groceries online? For example, do consumers expect all the information presented online to be the same as the retail food package label? When there is a picture of a product label online, do consumers expect the picture of the label to be the same as the label on the retail food package? Please provide any data and evidence to support your response.

3.2 To what extent, and how, do consumers use nutrition, ingredient, and major food allergens information when grocery shopping online? For example, what percentage of consumers use the label to get information to support eating healthier? What percentage of consumers use the label information because of specific dietary concerns? We would be especially interested in demographic data on consumers who view label information when grocery shopping online. Please provide any data and evidence to support your response.

3.3 What do consumers find most challenging about navigating online shopping platforms for specific label information needs? Please provide any data and evidence to support your response.

3.4 What data are available on the most effective ways for presenting nutrition, ingredient, and major food allergens information specifically through online grocery shopping platforms (websites, mobile applications, etc.), so that consumers can easily access the information? For example, is there a specific format (*e.g.,* Nutrition Facts label format) that consumers find useful in an online grocery shopping platform? What are effective means of displaying this information on the platform (*e.g.,* link to additional product information, viewable on the top 50 percent of the web page) to ensure consumers have ready access? Please provide any data and evidence to support your response.

V. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. eMarketer Editors. ''In 2021, Online Grocery Sales Will Surpass $100 Billion'' Insider Intelligence, February 24, 2021, available at: *https://www.emarketer.com/content/2021-online-grocery-sales-will-surpass-100-billion.* Accessed on October 3, 2022.
2. FDA. ''Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling.'' January 2007. Available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-and-fda-dear-manufacturer-letter-regarding-food-labeling.* Accessed on October 3, 2022.
3. Pomeranz, Jennifer L., et al., ''Opportunities to Address the Failure of Online Food Retailers to Ensure Access to Required Food Labelling Information in the USA'', March 2022. Available at: *https://www.cambridge.org/core/journals/public-health-nutrition/article/opportunities-to-address-the-failure-of-online-food-retailers-to-ensure-access-to-required-food-labelling-information-in-the-usa/9520BF4CB0E2CDDF9760276729F0DBE2.* Accessed on October 3, 2022.
4. Olzenak, Kelly, et al., ''How Online Grocery Stores Support Consumer Nutrition Information Needs'', March 2022. Available at: *https://www.sciencedirect.com/science/article/pii/S1499404620305248.* Accessed on October 3, 2022.

Dated: April 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08543 Filed 4–21–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork