information for OTC monograph products, OTC monograph order requests, and the OTC Monograph User Fee Program have been approved under OMB control number 0910–0340. The information collections for submission of new drug applications and abbreviated new drug applications in 21 CFR part 314 are approved under OMB control number 0910–0001. The collections of information used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses under 21 CFR part 25 have been approved under OMB control number 0910–0322.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07767 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1052]

Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a request for information and comments on the development of an FDA Data and Technology Strategic Plan. As part of our User Fee Program commitments and Omnibus Bill requirements, FDA will develop and publish an FDA Data and Technology Strategic Plan by September 30, 2023. This plan will define and shape the future course of FDA's data and technology capabilities, building on the existing FDA Modernization Framework. The plan will also integrate Agency and center strategies.

DATES: Submit either electronic or written comments on the request for information and comments by May 15, 2023 to ensure that the Agency considers your comments before it begins work on the final version of the strategy.

ADDRESSES: You may submit comments 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–N–1052 for ''FDA Data and Technology Strategic Plan.'' 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.'' 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: Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, email: *Casi.Alexander@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a request for information and comments entitled ''FDA Data and Technology Strategic Plan; Request for Information and Comments.''

The Office of Digital Transformation (ODT) was established in September 2021 and reports directly to the Office of the Commissioner. ODT provides the vision and leadership in information technology, data, and cybersecurity needed to advance FDA's mission and strategic priorities. ODT has published a series of strategy documents known as

the FDA Modernization Framework. The framework includes the Technology Modernization Action Plan, Data Modernization Action Plan, Enterprise Modernization Action Plan, Cybersecurity Modernization Action Plan, and the Leadership Modernization Action Plan. The FDA Modernization Framework aims to develop an integrated technology, data, cybersecurity, business, and leadership approach to advancing FDA's public health mission in collaboration with industry.

As part of the FDA's fulfillment of requirements in section 3627 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), and commitments described in section IV.A.2. of the ''PDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (PDUFA VI commitment letter), FDA will work with industry as it develops a comprehensive framework for guiding the Agency's work and allocating annual technology budgets and resources. The FDA Data and Technology Strategic Plan, covering Fiscal Years 2024–2027, will define and shape the future course of FDA's data and technology capabilities as FDA transitions to the next phase of its journey. FDA will take an iterative approach to strategy development, starting with gathering input, then, sharing a draft of the strategic plan for comment and finally, considering inputs provided before publishing a final version of the strategic plan. FDA will focus on the outcomes to empower the Agency to meet its mission, building on the existing FDA Modernization Framework and integrating Agency and center strategies. FDA will engage internal and external stakeholders early and often throughout this process. FDA plans to incorporate stakeholder input as the Agency engages with internal and external stakeholders across the remainder of this fiscal year including through two **Federal Register** notices for information and comment (this one and a second one for comment on the draft strategy). Stakeholder input is crucial for developing a comprehensive plan that best meets the needs and goals of industry and the Agency.

II. Requested Information and Comments

Interested persons are invited to provide detailed comments to ODT (see **ADDRESSES**) on the following aspects of the development of FDA's Agency-wide Data and Technology Strategic Plan. To facilitate input, FDA has developed a series of questions in this section. The questions are not meant to be exhaustive, and FDA is also interested in any other pertinent information stakeholders would like to share on this topic. This feedback will help inform the Agency's strategy development. FDA encourages stakeholders to provide the specific rationale and basis for their comments, including any available supporting data and information. FDA will publish another notice in the **Federal Register** requesting comments once the Data and Technology Modernization Strategy is developed.

1. What are up to three outcomes the FDA Data and Technology Strategic Plan can help you achieve, *e.g.,* speed to market?
2. What are up to three challenges you are facing while trying to achieve these outcomes?
3. What data and technical capabilities could FDA strengthen to help support its public health mission?
4. What opportunities or risks do you foresee for the FDA Data and Technology Strategic Plan?
5. What changes or trends in your industry could impact the FDA Data and Technology Strategic Plan?
6. How might FDA best communicate and engage stakeholders in developing and implementing the strategy?

Dated: April 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07766 Filed 4–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1043]

Exemption of Certain Categories of Biological Products From Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is issuing a final order to exempt certain categories of biological products from certain reporting requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Specifically, each person who registers with FDA with regard to a drug is required to report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution; however, certain biological products or categories of biological products may be exempted by order from these reporting requirements if FDA determines that applying such reporting requirements is not necessary to protect the public health. This final order exempts two categories of biological products from these reporting requirements because the Agency has determined that applying such requirements is not necessary to protect the public health.

DATES: This order is effective May 15, 2023.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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: Jessica Gillum, 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—Reporting Requirements Under Section 510(j)(3) of the FD&C Act

On March 27, 2020, the CARES Act (Pub. L. 116–136) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019. In addition, the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, enhancing FDA's visibility into drug supply chains.

Section 3112(e) of the CARES Act added new paragraph (3) to section 510(j) of the FD&C Act (21 U.S.C. 360(j)(3)), which requires that each person who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA on the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution. These reporting requirements in section 510(j)(3)(A) of the FD&C Act enhance FDA's ability to address drug shortages by enabling the Agency to identify manufacturing sites impacted and develop potential options to remediate shortage risks to the product supply chain.

Under section 510(j)(3)(B) of the FD&C Act, FDA may exempt certain