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

biological products or categories of biological products regulated under section 351 of the Public Health Service Act (42 U.S.C. 262) from some or all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act, if FDA determines that applying such reporting requirements is not necessary to protect the public health.

In the **Federal Register** of October 27, 2021 (86 FR 59395), FDA published a proposed order entitled ''Exemption of Certain Categories of Biological Products from Certain Reporting Requirements Under the Federal Food, Drug, and Cosmetic Act'' in which FDA proposed to exempt certain categories of biological products from certain reporting requirements under FD&C Act as amended by the CARES Act. Specifically, FDA proposed to exempt the following two categories of biological products from all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act because the Agency determined that applying such requirements is not necessary to protect the public health: (1) Blood and blood components for transfusion and (2) cell and gene therapy products, where one lot treats a single patient.

II. Comments on the Proposed Order and FDA Response

In response to the October 27, 2021, proposed order, FDA received one comment by the close of the comment period. We describe and respond to the comment in this section of the document.

(Comment 1) One comment recommends that FDA expand the proposed order to also exempt ''made-to-stock'' cell and gene therapy products. The comment asserts that the supply chains for such products are ''well-established and well-understood'' from information in the biologics license applications (BLAs), and generally do not involve wholesale distributors, brokers, or other intermediaries.

(Response) We decline to expand the order to exempt ''made to stock'' cell and gene therapy products. ''Made-to-stock'' cell and gene therapy products are generally manufactured in lots or batches for commercial distribution, based on projected product demand, and they are not typically for use where one lot treats a single patient. We disagree that the supply chains for ''made-to-stock'' cell and gene therapy products are well-established and well-understood. Even though they may not involve wholesale distributors, brokers, or other intermediaries, FDA has limited visibility into the supply chains for such products. We reiterate that the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. When FDA is notified of an impending manufacturing problem that could lead to a supply interruption,[1] having information about the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed for commercial distribution, as reported under section 510(j)(3)(A) of the FD&C Act, can provide insight into how much manufacturing typically occurs at the affected facility and whether the problem may lead to a drug shortage. Furthermore, these data can help the Agency to identify and measure supply chain vulnerabilities that could be longer term risk factors for drug shortages. We anticipate that requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of ''made-to-stock'' cell and gene therapy products manufactured, prepared, propagated, compounded, or processed for commercial distribution will improve FDA's visibility into the supply chains for these products and enhance the Agency's ability to identify, prevent, and mitigate possible shortages. There is not an adequate basis at this time for FDA to determine that applying such reporting requirements to this category of biological products is not necessary to protect the public health. Thus, there is not an adequate basis to exempt ''made-to-stock'' cell and gene therapy products from the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act.

III. Exempted Categories of Biological Products

FDA is finalizing the order to exempt the following two categories of biological products from all of the reporting requirements under section 510(j)(3)(A) of the FD&C Act pursuant to section 510(j)(3)(B) of the FD&C Act because FDA has determined that applying such reporting requirements is not necessary to protect the public health:

- Blood and blood components for transfusion; and
- Cell and gene therapy products, where one lot treats a single patient.

[1] See, *e.g.,* section 506C(a) of the FD&C Act (21 U.S.C. 355d) (notifications of discontinuance or interruption in the production of life-saving drugs).

A. Blood and Blood Components for Transfusion

In accordance with section 510(j)(3)(B) of the FD&C Act, this order exempts blood and blood components for transfusion from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Generally, registered blood establishments are inspected on a biennial basis by the Agency. There are approximately 1,900 registered blood establishments that manufacture blood and blood components for transfusion, all located in the United States, as well as a small number of United States military blood establishments that are located internationally in order to provide blood and blood components to United States military personnel onsite when needed. The supply chains for blood and blood components for transfusion are well-established and well-understood based on the nature of the products; namely, blood is collected from human donors via venipuncture, separated into components (if applicable), and stored at specified temperatures and under the complete control of each blood establishment. Additionally, supply chains for blood and blood components for transfusion are controlled and secure from initial donation to final product delivery to the transfusion site and, generally, do not involve wholesale distributors, brokers, or other intermediaries. Further, many registered blood establishments voluntarily submit the amount of blood and blood components for transfusion manufactured as part of the Health and Human Services National Blood Collection and Utilization Survey (NBCUS), which, historically, has a high response rate.[2]

[2] See *https://doi.org/10.1111/trf.16449.* The response rate for the 2019 NBCUS was 94 percent for community-based blood collection facilities and 84 percent for hospital-based blood collection facilities.

B. Cell and Gene Therapy Products, Where One Lot Treats a Single Patient

In accordance with section 510(j)(3)(B) of the FD&C Act, this order exempts cell and gene therapy products, where one lot treats a single patient, from the reporting requirements under section 510(j)(3)(A) of the FD&C Act. In light of FDA's existing visibility into the supply chain for this category of products, requiring registrants to report annually under section 510(j)(3)(A) of the FD&C Act on the amount of such products manufactured, prepared, propagated, compounded, or processed for commercial distribution, is not needed to enhance the Agency's ability to identify, prevent, and mitigate possible shortages. As such, FDA has determined that applying the reporting requirements under section 510(j)(3)(A) of the FD&C Act to this category of biological products is not necessary to protect the public health.

Manufacturers of cell and gene therapy products, where one lot treats a single patient, maintain a highly controlled and secure supply chain from initial request for treatment of a patient to final product delivery to the site where the treatment occurs. This is because, due to the nature of these products, manufacturers implement strict chain of identity procedures to track products through the manufacturing process, to make sure the correct product gets to the correct patient. Additionally, the supply chains for these products are well-established and well-understood from information described in the BLA, and generally do not involve wholesale distributors, brokers, or other intermediaries.

Additionally, pursuant to § 600.81 (21 CFR 600.81), the Agency generally receives lot distribution reports every 6 months from BLA holders. Specifically, reports submitted to the Agency under § 600.81 include, among other information, the fill lot numbers for the total number of dosage units of each strength or potency distributed, the label lot number (if different from fill lot number), the number of doses in fill lot/label lot, and the date of release of fill lot/label lot for distribution. For this category of biological products, because one lot treats a single patient, the lot distribution reports submitted to the Agency under § 600.81 represent the amount of product manufactured for commercial distribution, and additional reporting of such information under section 510(j)(3)(A) of the FD&C Act would be redundant.

IV. Paperwork Reduction Act of 1995

This final order contains information collection provisions that 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 information collection provisions of this final order are approved under 0910–0045.

V. Effective Date

This final order is effective 30 days after its date of publication in the **Federal Register**.

Dated: April 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07772 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–2016–D–1254]

Assessing Adhesion With Transdermal and Topical Delivery Systems for Abbreviated New Drug Applications; Revised 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 revised draft guidance for industry entitled ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs'' (Revision 2). This draft guidance (Revision 2) revises the Revision 1 draft guidance of the same name, which was announced in the **Federal Register** on October 10, 2018. This revised draft guidance provides recommendations for the design and conduct of studies evaluating the adhesion performance of a transdermal or topical delivery system (collectively referred to as TDS). Depending on the objectives of a generic TDS product development program, applicants may choose to evaluate TDS adhesion in studies performed to evaluate TDS adhesion only, or in studies performed with a combined purpose (*e.g.,* for the simultaneous evaluation of adhesion and bioequivalence (BE) with pharmacokinetic (PK) endpoints). The recommendations in this revised draft guidance relate to studies submitted in support of an abbreviated new drug application (ANDA).

DATES: Submit either electronic or written comments on the draft guidance by June 12, 2023 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 2016–D–1254 for ''Assessing Adhesion With Transdermal and Topical Delivery Systems for ANDAs.'' 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.