under the PRA because it entails no burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument (see 5 CFR 1320.3(h)(1)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
§ 822.31; Manufacturer records	5	1	5	20	100
§ 822.32; Investigator records	15	1	15	5	75
Total					175

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Explanation of Recordkeeping Burden Estimate: FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with PS.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Our estimated burden for the information collection reflects an overall decrease of 4,780 hours and a corresponding decrease of 145 responses. We believe these adjustments more accurately reflect the current number of requests associated with postmarket surveillance of medical devices.

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24232 Filed 11–4–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0776]

Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; 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 final guidance entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate investigational new drug application (IND). The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2021–D–0776 for ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

FDA is announcing the availability of a document entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial; Guidance for Industry.'' The guidance document provides recommendations to sponsors interested in studying multiple versions of a cellular or gene therapy product in an early phase clinical trial for a single disease. Sponsors have expressed interest in gathering preliminary evidence of safety and activity using multiple versions of a cellular or gene therapy product in a single clinical trial, where each version of the product is distinct and is generally submitted to FDA in a separate IND. The objective of these early phase clinical studies is to guide which version(s) of the product to pursue for further development in later phase studies. Thus, these studies are not intended to provide primary evidence of effectiveness to support a marketing application and generally are not adequately powered to demonstrate a statistically significant difference in efficacy between the study arms. The guidance provides recommendations for conducting such studies, including how to organize and structure the INDs, submit new information, and report adverse events.

In the **Federal Register** of September 30, 2021 (86 FR 54207), FDA announced the availability of the draft guidance entitled ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early Phase Clinical Trial.'' FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. Changes to the guidance include clarifying how to continue the umbrella trial after a study arm has been closed and adding examples of changes that result in multiple versions of a cellular or gene therapy product. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated September 2021.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Studying Multiple Versions of a Cellular or Gene Therapy Product in an Early-Phase Clinical Trial.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 and Form FDA 1572 have been approved under OMB control number 0910–0014.

III. Electronic Access

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

Dated: November 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–24112 Filed 11–4–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2671]

Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; 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 virtual public meeting entitled ''Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023'' to allow supply chain stakeholders an opportunity to share their perspectives. The topics to be discussed are stakeholder experiences with implementation and overall readiness regarding implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023, standards for the interoperable data exchange of product tracing information, requests for product tracing information or verification from FDA for the purpose of investigating suspect or illegitimate products or for recalls, steps taken to build capacity for package-level tracing, pharmaceutical distribution supply chain best practices, and, in general, the impact that the Drug Supply Chain Security Act (DSCSA) requirements would have on public health, including patient safety and access to prescription drugs, and on