Supply Chain Security Act (FASCSA) Orders. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Marissa Ryba, Procurement Analyst, at telephone 314–586–1280, or *Marissa.Ryba@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and any Associated Form(s)

9000–0205, Implementation of Federal Acquisition Supply Chain Security Act (FASCSA) Orders

B. Need and Uses

This clearance covers the information that offerors and contractors must submit to comply with the following FAR requirements:

a. FAR 52.204–29, Federal Acquisition Supply Chain Security Act Orders-Representation and Disclosures. This provision prohibits contractors from providing or using as part of the performance of the contract any covered article, or any products or services produced or provided by a source, if the covered article or the source is subject to an applicable FASCSA order identified in the clause at FAR 52.204–30(b)(1).

By submitting an offer, offerors are representing compliance with the prohibition. If an offeror cannot represent compliance with the prohibition, then the offeror must disclose the following information in accordance with 52.204–29(e):

(1) Name of the product or service provided to the Government;

(2) Name of the covered article or source subject to an FASCA order;

(3) If applicable, name of the vendor, including the Commercial and Government Entity code and unique entity identifier (if known), that supplied the covered article or the product or service to the Offeror;

(4) Brand;

(5) Model number (original equipment manufacturer number, manufacturer part number, or wholesaler number);

(6) Item description;

(7) Reason why the applicable covered article or the product or service is being provided;

b. FAR 52.204–30, Federal Acquisition Supply Chain Security Act Orders-Prohibition. This clause requires contractors to provide a report to the Government within 3 business days if the contractor identifies that the contractor or any-tier subcontractor, delivered or used a covered article or product or service subject to a FASCSA order. The report requires the following information:

(1) Contract number;

(2) Order number(s), if applicable;

(3) Name of the product or service provided to the Government;

(4) Name of the covered article or source subject to a FASCSA order;

(5) If applicable, name of the vendor, including the Commercial and Government Entity code and unique entity identifier (if known), that supplied the covered article or the product or service to the Contractor;

(6) Brand;

(7) Model number (original equipment manufacturer number, manufacturer part number, or wholesaler number);

(8) Item description; and

(9) Any readily available information about mitigation actions undertaken or recommended.

The contractor must also submit additional information within 10 days of submitting the first report identifying any further available information about mitigation actions undertaken or recommended. Additionally, the contractor shall describe the efforts it undertook to prevent submission and any additional efforts to prevent future submission of the covered article or the product or service produced or provided by a source subject to an applicable FASCSA order.

FAR provision 52.204–29. Information collected under will be by the government to determine whether to seek a waiver from a FASCSA order issued under the authority of the Federal Acquisition Supply Chain Security Act of 2018.

FAR clause 52.204–30 will Information collected will be used by the contracting officer working with the requirement activity to determine whether it is necessary to take further action and modify the contract.

C. Annual Burden

Respondents/Recordkeepers: 6,113.

Total Annual Responses: 1.

Total Burden Hours: 12,226.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0205, Implementation of Federal Acquisition Supply Chain Security Act (FASCSA) Orders.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2023–28419 Filed 12–22–23; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2818]

Rare Diseases: Considerations for the Development of Drugs and Biological Products; 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 for industry entitled ''Rare Diseases: Considerations for the Development of Drugs and Biological Products.'' This guidance is intended to assist sponsors of drugs and biological products for treatment of rare diseases in conducting efficient and successful drug development programs through a discussion of selected issues commonly encountered in rare disease drug development. This guidance finalizes the draft guidance entitled ''Rare Diseases: Common Issues in Drug Development'' issued on February 1, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on December 26, 2023.

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–2015–D–2818 for ''Rare Diseases: Considerations for the Development of Drugs and Biological Products.'' 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 this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Andrea Bell-Vlasov, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6484, Silver Spring, MD 20993–0002, 240–402–4977; or Anne Taylor, 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 final guidance for industry entitled ''Rare Diseases: Considerations for the Development of Drugs and Biological Products.'' This guidance is intended to assist sponsors of drugs and biological products for treatment of rare diseases in conducting efficient and successful product development programs through a discussion of selected issues commonly encountered in rare disease drug development. This final guidance addresses important aspects of drug and biological product development to support the proposed clinical investigation(s), including nonclinical pharmacology/toxicology; trial design and endpoint considerations to ensure quality and interpretability of data; standard of evidence to establish safety and effectiveness; and drug manufacturing considerations during drug development.

This guidance finalizes the draft guidance entitled ''Rare Diseases: Common Issues in Drug Development'' issued February 1, 2019 (84 FR 1156). Changes made from the draft to the final guidance took into consideration comments received. Major changes include the removal of the natural history section (because this is addressed in a separate guidance), additional considerations regarding nonclinical studies, information on the use of external controls and early randomization, a section discussing safety considerations, information on changes to drug substance or manufacturing process, and sections discussing participation of patients/patient groups in drug development programs and pediatric considerations in rare disease drug development.

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 ''Rare Diseases: Considerations for the Development of Drugs and Biological Products.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521).

The following collections of information in the final guidance have been approved under OMB control number 0910–0001:

• Submitting under 21 CFR 314.50(c)(1)(iv) and (d)(3) (§ 314.50(c)(1)(iv) and (d)(3)) a summary of the nonclinical pharmacology and toxicology section and the human pharmacokinetics and bioavailability section of new drug application (NDAs);

• Submitting under § 314.50(d)(1)(i) chemistry, manufacturing, and controls information, including the drug substance, for the content and format of an NDA for rare diseases; and

• Submitting under § 314.50(d)(5) and (d)(5)(iv) clinical data of a drug, including a description of any other data information relevant to an evaluation of the safety and effectiveness of a drug.

• Submissions under 21 CFR part 314, subpart H, to grant accelerated approval of new drugs for serious or life-threatening illnesses.

• Submissions under §§ 312.47 and 312.82 for requesting meetings with FDA about drug development programs.

The following collections of information in the final guidance have been approved under OMB control number 0910–0014:

• Submitting under 21 CFR 312.23(a)(6)(i) (§ 312.23(a)(6)(i)) a protocol for the duration of a trial and the criteria to enter a trial and under § 312.23(a)(6)(i), (a)(6)(iii)(d) and (g) a description of an estimate of patients that will be involved in a trial, including a description of the safety exclusions and a description of clinical procedures, laboratory, or other methods.

• Submitting under § 312.23(a)(3)(i) a brief introductory statement and general investigational plan, including the route of administration of a drug;

• Submitting under § 312.23(a)(7) and (a)(7)(iv)(a) chemistry, manufacturing, and controls information for the content and format of an investigational new drug application (IND) and the safety and effectiveness of such information;

• Submitting under § 312.23(a)(8) and (a)(8)(i) pharmacology, toxicology, and drug disposition information for rare diseases;

• Submitting under 312.23(a)(10)(iii) plans for assessing pediatric safety and effectiveness;

• Submitting under § 312.32(c)(1) IND safety reports;

• Submissions under §§ 312.305(b) and 312.310(b) for expanded access uses and treatment of an individual patient.

The collections of information in 21 CFR part 316 for submitting the content and format of NDAs for orphan drugs have been approved under OMB control number 0910–0167. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information pertaining to expedited review programs for serious conditions, accelerated approval, breakthrough therapy-designation, and fast-track designation, have been approved under OMB control number 0910–0765. The collections of information in 21 CFR part 58 pertaining to good laboratory practices have been approved under OMB control number 0910–0119. The collection of information pertaining to current good manufacturing practices have been approved under OMB control number 0910–0139.

III. Electronic Access

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

Dated: December 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28310 Filed 12–22–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–30D]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 25, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0313 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Blood Collection & Utilization Survey (NBCUS)

Type of Collection: Revision

OMB No. 0990–30D–0313 Office of the Assistant Secretary for Health/HHS

Abstract

The Office of the Assistant Secretary for Health (OASH) is requesting approval for a three-year revised information collection request (ICR) titled ''National Blood Collection & Utilization Survey (NBCUS).'' The NBCUS is a biennial survey that includes a core of standard questions on blood collection, processing, and utilization practices. Questions on transfusion-transmitted infections, transfusion associated circulatory overload, acute hemolysis, delayed hemolysis, and severe allergic reactions are also included in the survey. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. blood collections and transfusions for understanding the dynamics of blood safety and availability. In 2023, two sections were removed from the survey related to the impact of the COVID–19 pandemic on the blood supply during the course of 2020.

Survey respondents will consist of blood collection centers and hospitals that perform blood transfusions, except those reporting fewer than 100 inpatient surgeries per year. For the purposes of this ICR, federal burden is only being placed on facilities located within the fifty states and the District of Columbia. The total estimated burden is 5,106 hours.