(OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry and Food and Drug Administration Staff; Combination Products: How to Write a Pre-Request For Designation

OMB Control Number 0845—Extension

The purpose of this guidance is to clarify the type of information the Office of Combination Products (OCP) recommends that a sponsor include in a Pre-RFD. This goal of this guidance is to assist sponsors in obtaining a preliminary assessment from the U.S. Food and Drug Administration (FDA or Agency) through the Pre-RFD process. The Pre-RFD process is available to provide informal, non-binding feedback regarding the regulatory identity or classification of a human medical product as a drug, device, biological product, or combination product. In addition, this informal process provides information about a non-combination or combination product's assignment to the appropriate Agency Center (Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), or Center for Biologics Evaluation and Research (CBER)) for premarket review and regulation. Specifically, this guidance explains the Pre-RFD process at the Office of Combination Products (OCP) and helps a sponsor understand the type of information to provide in a Pre-RFD. This guidance describes how to prepare a Pre-RFD submission. The guidance provides recommendations regarding the information that should be submitted in a Pre-RFD request and procedures that should be followed for meetings or conference calls between the Office of Combination Products, the Centers, and industry representatives or sponsors.

The proposed collections of information are necessary to allow the Agency to receive Pre-RFD requests in order to implement this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pre-RFD Submissions	83	1	83	12	996
Pre-RFD Meetings	83	1	83	1	83
Total					1,079

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

Our estimated burden for the information collection reflects an overall decrease of 689 hours. We attribute this adjustment to a decrease in response time for the number of submissions we received over the past 3 years.

Dated: March 16, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06031 Filed 3–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1106]

Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency; Immediately in Effect 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 guidance for industry entitled ''Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.'' Due to the Coronavirus Disease 2019 (COVID–19) pandemic, FDA has received a number of queries concerning compounding of alcohol-based hand sanitizers. The Agency is issuing this guidance to communicate its policy for the temporary compounding of certain alcohol-based hand sanitizer products by pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this notice and the guidance as *compounders*) for the duration of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 23, 2020. The guidance document is immediately in

effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

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–2020–D–1106 for ''Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.'' 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.

- 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.

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. 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: Rosilend Lawson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–6223.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled ''Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.'' Due to the COVID–19 pandemic and the resulting public health concerns, FDA has received a number of queries concerning compounding of alcohol-based hand sanitizers. We understand that some consumers and healthcare professionals are currently experiencing difficulties accessing alcohol-based hand sanitizers containing at least 60 percent alcohol or 70 percent isopropyl alcohol. We are also aware of reports that some consumers are producing hand sanitizers for personal use; the Agency lacks information on the methods being used to prepare such products and whether they are safe for use on human skin. We further recognize that pharmacists in State-licensed pharmacies or Federal facilities and registered outsourcing facilities (referred to collectively in this notice and the guidance as *compounders*), relative to untrained consumers, are more familiar with appropriate standards and methods for producing drug products.

The Agency is issuing this guidance to communicate a policy for the temporary compounding of certain alcohol-based hand sanitizer products by compounders for consumer use and for use as healthcare personnel hand rubs for the duration of the public health emergency declared by the Secretary of Health and Human Services on January 31, 2020. In light of the public health emergency posed by COVID–19, FDA has determined that prior public participation for this guidance is not feasible or appropriate and is issuing this guidance without prior public comment (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i)) and 21 CFR 10.115(g)(2)). Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

II. Significance of Guidance

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 ''Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency.'' 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.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information 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 collection of information for ''Current Good Manufacturing Practices for Finished Pharmaceuticals and Medical Gases'' has been approved under OMB control number 0910–0139. The collection of information for ''Postmarketing Adverse Drug Experience Reporting'' has been approved under OMB control number 0910–0230. The collection of information for ''MedWatch: Adverse Event and Product Experience Reporting System (Paper-Based)'' has been approved under OMB control number 0910–0291. The collection of information for ''Format and Content Requirements for Over-the-Counter Drug Product Labeling'' has been approved under OMB control number 0910–0340. The collection of information for ''FDA Adverse Event and Products Experience Reports; Electronic Submissions'' has been approved under OMB control number 0910–0645. The collection of information for ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' has been approved under OMB control number 0910–0800.

IV. Electronic Access

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

Dated: March 17, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05959 Filed 3–20–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Public Comments on Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Request for public comment.

SUMMARY: The Office of the Assistant Secretary for Health in the Department of Health and Human Services seeks public comment regarding Section 209 of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act.

Congress passed the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) in June 2019. Section 209 of this legislation states that the Secretary of Health and Human Services shall submit to Congress a report containing recommendations related to maintaining an adequate national blood supply. The legislation poses four specific questions regarding the adequacy of the national blood supply. HHS welcomes any public feedback related to how these questions should be addressed and/or potential solutions. The set of questions is available in the **SUPPLEMENTARY INFORMATION** section below.

DATES: To be assured consideration, electronic or written/paper comments must be submitted no later than midnight Eastern Standard Time (EST) on April 22, 2020.

ADDRESSES: Individuals are encouraged to submit responses electronically to *ACBTSA@hhs.gov*. Please indicate ''RFI RESPONSE'' in the subject line of your email. Written responses should be addressed to: U.S. Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Room L600, Washington, DC 20024 Attn: ACBTSA–PAHPAIA Sec. 209. Mailed paper submissions and electronic submissions received after the deadline will not be reviewed. Responses to this notice are not offers and cannot be accepted by the federal government to form a binding contract or issue a grant.

FOR FURTHER INFORMATION CONTACT: Mr. James Berger, Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, (202) 795–7608.

SUPPLEMENTARY INFORMATION:

(1) Challenges associated with the continuous recruitment of blood donors (including those newly eligible to donate);

(2) Ensuring the adequacy of the blood supply in the case of public health emergencies;

(3) Implementation of the transfusion transmission monitoring system; and

(4) Other measures to promote safety and innovation, such as the development, use, or implementation of new technologies, processes, and procedures to improve the safety and reliability of the blood supply.

Dated: March 11, 2020.

James J. Berger,

Senior Advisor for Blood and Tissue Policy, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–06047 Filed 3–20–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

[OIG–1810–N]

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This notice replaces all language in Part Q (Office of the Secretary) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (HHS or the Department), Office of Inspector General (OIG), (published March 15, 2016).

SUPPLEMENTARY INFORMATION: The Statement of Organization, Functions, and Delegations of Authority conforms to and carries out the statutory requirements for operating OIG. The organizational changes reflected in this notice are primarily to realign the functions within OIG to better reflect the current work environment and priorities and to more clearly delineate responsibilities for the various activities within OIG's offices.

OIG was established by law as an independent and objective oversight unit of the Department to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations. In furtherance of this mission, the organization:

- Conducts and supervises audits, investigations, evaluations, and inspections relating to HHS programs and operations;
- identifies systemic weaknesses giving rise to opportunities for fraud and abuse in HHS programs and operations and makes recommendations to prevent their recurrence;
- leads and coordinates activities to prevent and detect fraud and abuse in HHS programs and operations;
- detects wrongdoers and abusers of HHS programs and beneficiaries so appropriate remedies may be brought to