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.gpo.gov/fdsys/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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rick Ensor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6652, Silver Spring, MD 20993–0002, 240–402–2733, or Stephen Ripley, 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FDA is announcing the availability of a draft guidance for industry entitled ''Drug Master Files.'' Once finalized, this guidance will provide FDA's current thinking on DMFs, which are submissions to FDA that may be used to provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products. DMFs are submitted solely at the discretion of their holders and are not required by statute or regulation. After submission, information in DMFs can be incorporated by reference into applications [1] or other DMFs submitted to FDA.

This draft guidance, when finalized, will revise the guidance for industry ''Drug Master Files: Guidelines'' that published in September 1989. This update includes a change in FDA's contact person for the guidance, new procedures for DMFs referenced in abbreviated new drug applications that reflect commitments under the Generic Drug User Fee Amendments of 2012 (Pub. L. No. 112–144, Title III; reauthorized in 2017, Pub. L. 115–52), more detailed instructions regarding the submission of original DMFs versus amendments, reference to the electronic submission requirements under section 745A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1) that apply to certain DMFs, removal of Type I as a DMF category, and clarification and reorganization of material associated with Type III and Type IV DMFs.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Drug Master Files.'' 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

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: October 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–22821 Filed 10–18–19; 8:45 am]

BILLING CODE 4164–01–P

[1] This guidance focuses on DMFs under 21 CFR 314.420 that are used to support new drug applications, abbreviated new drug applications, and investigational new drug applications under the FD&C Act and DMFs and other master files under 21 CFR 601.51(a) that are used to support biologics license applications under the Public Health Service Act. Additionally, information contained in DMFs can generally be referenced in premarket submissions for devices (*e.g.,* premarket approvals) and animal drugs (*e.g.,* new animal drug applications).

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0111]

Agency Information Collection Activities: Arrival and Departure Record (Forms I–94, I–94W) and Electronic System for Travel and Authorization (ESTA)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and must be submitted (no later than November 20, 2019) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP

programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (84 FR 41727) on August 15, 2019, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Arrival and Departure Record, Nonimmigrant Visa Waiver Arrival/Departure, Electronic System for Travel Authorization (ESTA).

OMB Number: 1651–0111.

Form Numbers: CBP Forms I–94 and I–94W.

Current Actions: This submission is being made to extend the expiration date of this information collection with no changes to the burden hours or to the information collected.

Type of Review: Extension (with no change).

Affected Public: Individuals.

Abstract: Forms I–94 (Arrival/Departure Record) and I–94W (Nonimmigrant Visa Waiver Arrival/Departure Record) are used to document a traveler's admission into the United States. These forms are filled out by aliens and are used to collect information on citizenship, residency, passport, and contact information. The data elements collected on these forms enable the Department of Homeland Security (DHS) to perform its mission related to the screening of alien visitors for potential risks to national security and the determination of admissibility to the United States. The Electronic System for Travel Authorization (ESTA) applies to aliens seeking to travel to the United States under the Visa Waiver Program (VWP) and requires that VWP travelers provide information electronically to CBP before embarking on travel to the United States without a visa. Travelers who are entering the United States under the VWP in the air or sea environment, and who have a travel authorization obtained through ESTA, are not required to complete the paper Form I–94W. I–94 is provided for by 8 CFR 235.1(h), ESTA is provided for by 8 CFR 217.5.

Recent Changes

On November 27, 2017, the Secretary of State designated DPRK, as a State Sponsor of Terrorism, or SST. Countries determined by the Secretary of State ''to have repeatedly provided support for acts of international terrorism'' are considered to have been designated as ''state sponsors of terrorism.''

Section 217(a)(12)(A)(i) of the Immigration and Nationality Act, 8 U.S.C. 1187(a)(12)(A)(i) bars from travel under the Visa Waiver Program (VWP) nationals of VWP program countries who have ''been present, at any time on or after March 1, 2011,'' . . . ''in a country that is designated by the Secretary of State'' as a SST.

To meet the requirements and intent of the law and to keep ESTA and Form I–94W aligned, DHS is strengthening the security of the United States through enhancements to the ESTA application, and Form I–94W. Existing questions that request information from applicants/enrollees about countries to which they have traveled on or after March 1, 2011; countries of which they are citizens/nationals; and countries for which they hold passports are being revised to include, the DPRK.

Under the Emergency Clearance request process DHS has recently added DPRK to the following question to ESTA and Form I–94W (no change has been made to Form I–94): ''Have you traveled to, or been present in Iran, Iraq, Syria, Sudan, Libya, Somalia, Yemen, or the Democratic People's Republic of Korea (North Korea) on or after March 1, 2011? If yes, provide the country, date(s) of travel, and reason for travel.''

Form I–94 (Arrival and Departure Record)

Estimated Number of Respondents: 4,387,550.

Estimated Time per Response: 8 minutes.

Estimated Burden Hours: 583,544.

Estimated Annual Cost to Public: $26,325,300.

I–94 Website

Estimated Number of Respondents: 3,858,782.

Estimated Time per Response: 4 minutes.

Estimated Annual Burden Hours: 254,679.

Form I–94W (Nonimmigrant Visa Waiver Arrival/Departure)

Estimated Number of Respondents: 941,291.

Estimated Time per Response: 16 minutes.

Estimated Annual Burden Hours: 251,325.

Estimated Annual Cost to the Public: $5,647,746.

Electronic System for Travel Authorization (ESTA)

Estimated Number of Respondents: 23,010,000.

Estimated Time per Response: 23 minutes.

Estimated Total Annual Burden Hours: 8,812,830.

Estimated Annual Cost to the Public: $265,020,000.

Dated: October 16, 2019.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2019–22861 Filed 10–18–19; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0008]

Agency Information Collection Activities: Application for Identification Card

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border