

Dated: September 14, 2018.

Martique Jones,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory
Affairs.

[FR Doc. 2018–20372 Filed 9–18–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3152]

Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration,
HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Postapproval Changes to Drug Substances; Draft Guidance for Industry; Availability” that appeared in the *Federal Register* of September 11, 2018. The document announced a draft guidance that provides recommendations to holders of approved new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files and veterinary master files who may want to make a change to the drug substance manufacturing process during the drug product application postapproval period. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Tuesday, September 11, 2018 (83 FR 45944), in FR Doc. 2018–19666, on page 45944, the following correction is made:

On page 45944, in the first column, in the header of the document, and also in the third column under *Instructions*, “Docket No. FDA–2018–D–3151” is corrected to read “Docket No. FDA–2018–D–3152”.

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20317 Filed 9–18–18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0029]

Agency Information Collection Activities: Application for Foreign- Trade Zone Admission and/or Status Designation, and Application for Foreign-Trade Zone Activity Permit

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 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 will be accepted no later than October 19, 2018 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* (Volume 83 FR Page 23286) on May 18, 2018, 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: Application for Foreign-Trade Zone Admission and/or Status Designation, and Application for Foreign-Trade Zone Activity Permit.

OMB Number: 1651–0029.

Form Numbers: 214, 214A, 214B, 214C, and 216.

Type of Review: Extension (without change).

Action: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Forms 214, 214A, 214B, 214C, and 216.

Affected Public: Businesses.

Abstract: Foreign trade zones (FTZs) are geographical enclaves located within the geographical limits of the United States but for tariff purposes are considered to be outside the United States. Imported merchandise may be brought into FTZs for storage, manipulation, manufacture or other processing and subsequent removal for exportation, consumption in the United States, or destruction. A company bringing goods into an FTZ has a choice of zone status (privileged/non-privileged foreign, domestic, or zone-

restricted), which affects the way such goods are treated by Customs and Border Protection (CBP) and treated for tariff purposes upon entry into the customs territory of the U.S.

CBP Forms 214, 214A, 214B, and 214C, which make up the *Application for Foreign-Trade Zone Admission and/or Status Designation*, are used by companies that bring merchandise into an FTZ to register the admission of such merchandise into FTZs and to apply for the appropriate zone status. CBP Form 216, *Foreign-Trade Zone Activity Permit*, is used by companies to request approval to manipulate, manufacture, exhibit, or destroy merchandise in an FTZ.

These FTZ forms are authorized by 19 U.S.C. 81 and provided for by 19 CFR 146.22, 146.32, 146.39, 146.40, 146.41, 146.44, 146.52, 146.53, and 146.66. These forms are accessible at: <http://www.cbp.gov/newsroom/publications/forms>.

Form 214, Application for Foreign-Trade Zone Admission and/or Status Designation

Estimated Number of Respondents: 6,749.

Estimated Number of Annual Responses per Respondent: 25.

Estimated Total Annual Responses: 168,725.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 42,181.

Form 216, Application for Foreign-Trade Zone Activity Permit

Estimated Number of Respondents: 2,500.

Estimated Number of Annual Responses per Respondent: 10.

Estimated Total Annual Responses: 25,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 4,167.

Dated: September 13, 2018.

Seth D. Renkema,

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

[FR Doc. 2018-20306 Filed 9-18-18; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4384-DR; Docket ID FEMA-2018-0001]

Confederated Tribes of the Colville Reservation; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the Confederated Tribes of the Colville Reservation (FEMA-4384-DR), dated August 17, 2018, and related determinations.

DATES: The declaration was issued August 17, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646-2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated August 17, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage to the lands associated with the Confederated Tribes of the Colville Reservation resulting from flooding during the period of May 5 to May 28, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists for the Confederated Tribes of the Colville Reservation.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance and Hazard Mitigation for the Confederated Tribes of the Colville Reservation. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to Section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Timothy B. Manner, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas have been designated as adversely affected by this major disaster:

The Confederated Tribes of the Colville Reservation for Public Assistance.

The Confederated Tribes of the Colville Reservation are eligible to apply for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018-20320 Filed 9-18-18; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4385-DR; Docket ID FEMA-2018-0001]

Connecticut; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Connecticut (FEMA-4385-DR), dated August 20, 2018, and related determinations.

DATES: The declaration was issued August 20, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and