supplemental award is a key strategy for ORR to be prepared to meet its responsibility to provide shelter for Unaccompanied Children referred to its care by DHS and so that the U.S. Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

Statutory Authority: This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C. D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

Elizabeth Leo,

Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2018–18152 Filed 8–21–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2608]

Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public meeting entitled ''Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control (PQ/CMC).'' This public meeting is intended to provide members of the pharmaceutical industry and other interested stakeholders an opportunity to discuss with FDA, and provide input on, topics and issues related to standardized data for electronic submission of PQ/CMC data, as detailed in the 2017 **Federal Register** notice (FRN), ''Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies.'' FDA will use the information from the public meeting to improve the usability of the proposed data standards.

DATES: The public meeting will be held on October 19, 2018, from 9 a.m. to 4 p.m. Submit either electronic or written comments on this public meeting by November 16, 2018.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date. Docket comments previously submitted to the FRN (Docket No. FDA–2017–N–2166, *https://www.federalregister.gov/a/2017-14456*) noted in the **SUMMARY** section, should not be resubmitted, as these are already under consideration.

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–2018–N–2608 for ''Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control; Public Meeting.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.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.

FOR FURTHER INFORMATION CONTACT: Bryan Spells, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1117, Silver Spring, MD 20993–0002, *Bryan.Spells@fda.hhs.gov,* 240–402–6511; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Norman Gregory, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV–143), Rockville, MD 20855, *Norman.Gregory@fda.hhs.gov,* 240–402–0684; or Michael Kerrigan, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl. (HFV–143), Rockville, MD 20855, 240–402–0644, *Michael.Kerrigan@fda.hhs.gov.* Alternatively, send questions to the PQ–CMC mailbox: *PQ-CMC@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

PQ/CMC is a term used to describe manufacturing and quality control information submitted to FDA in support of submissions. PQ/CMC plays an integral part in the regulatory review process and life cycle management of pharmaceutical products. This information is primarily submitted in Module 3 of the Electronic Common Technical Document. The standardization of PQ/CMC data elements and terminologies will facilitate the Agency's transition to a streamlined electronic review environment.

FDA intends to identify and standardize data elements and terminologies for information commonly used and submitted in support of drug product applications. The impetus for this standardization effort was the provisions from the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 301 note) (Pub. L. 112–144), which authorized the Agency to require certain submissions to be submitted in a specified electronic format. The development of a structured format for PQ/CMC data will enable consistency in the content and format of PQ/CMC data submitted, thus providing a consistent look and feel for every application, and, in general, contributing to a more efficient and effective regulatory decision-making process by creating standardized data dictionaries.

As part of this effort, in 2017, FDA released a FRN presenting a ''Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies'' for public comment (*https://www.federalregister.gov/a/2017-14456*). FDA has subsequently utilized the comments received to revise and improve the data elements, terminologies, and definitions for PQ/CMC standardization. FDA intends to continue public engagement regarding PQ/CMC data standards development by holding the public meeting announced in this notice. After the public meeting, the Agency intends to issue a draft guidance on the standardization of PQ/CMC data elements and terminologies for electronic submissions.

II. Purpose of the Public Meeting

The purpose of the October 19, 2018, public meeting is to provide members of the pharmaceutical industry and other interested stakeholders an opportunity to discuss with FDA, and provide input on, topics and issues related to standardized data for electronic submission of PQ/CMC data, as detailed in the FRN, ''Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies,'' released in 2017 for public comment (*https://www.federalregister.gov/a/2017-14456*). FDA will use the information from the public meeting to improve the usability of the proposed data standards. The public meeting will focus on the current state of PQ/CMC standardization and its future development, to which the output and comments from this meeting will contribute. Topics of discussion may include:

- Ongoing development of PQ/CMC data elements and terminologies, including revisions informed by public response to the ''Draft Standardization'' FRN, developing the technical specifications for PQ/CMC data submissions, and upcoming development and testing of PQ/CMC data exchange mechanisms.
- Ongoing efforts to maximize harmonization of PQ/CMC standardization with other national and international data standardization activities sharing the same domain space as PQ/CMC (*e.g.,* International Organization for Standardization Identification of Medicinal Products (ISO IDMP) standards development, the European Medicines Agency's Substance, Product, Organisation and Referential (SPOR) Master Data initiative).
- An understanding of industry business practices regarding submission of PQ/CMC data which will help to inform development of PQ/CMC standardization.

FDA will consider all comments made at this meeting or received through the docket (see **ADDRESSES**).

III. Participating in the Public Meeting

Registration: To register to attend ''Standardized Data for Pharmaceutical Quality/Chemistry Manufacturing and Control; Public Meeting'' please register at: *https://www.eventbrite.com/e/standardized-data-for-pqcmc-public-meeting-registration-47224509780* by September 21, 2018. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by September 21, 2018, midnight Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Bryan Spells, 240–402–6511, email *Bryan.Spells@fda.hhs.gov* at least 7 days before the meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18080 Filed 8–21–18; 8:45 am]

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