

Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until FDA grants permission to market the device. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device Intercept Blood System for Platelets. Intercept Blood System for Platelets is indicated for *ex vivo* preparation of apheresis platelet components in order to reduce the risk of transfusion-transmitted infection including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease. Subsequent to this approval, the USPTO received patent term restoration applications for Intercept Blood System for Platelets (U.S. Patent Nos. 7,037,642 and 7,611,831) from Cerus Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 29, 2016, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of Intercept Blood System for Platelets represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO

requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Intercept Blood System for Platelets is 7,080 days. Of this time, 6,909 days occurred during the testing phase of the regulatory review period, while 171 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* August 2, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on July 26, 1995. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on August 2, 1995, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* July 1, 2014. The applicant claims August 15, 2014, as the date the premarket approval application (PMA) for Intercept Blood System for Platelets (PMA BP140143) was initially submitted. However, FDA records indicate that the complete PMA BP140143 was submitted on July 1, 2014.

3. *The date the application was approved:* December 18, 2014. FDA has verified the applicant's claims that PMA BP140143 was approved on December 18, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,640 days or 999 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in 21 CFR 60.30, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be

timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Dockets Management Staff (see **ADDRESSES**).

Dated: July 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-2166]

Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting comment on the draft standardized Pharmaceutical Quality/Chemistry Manufacturing and Control (PQ/CMC) data elements and terminologies for the electronic submission of PQ/CMC data. The establishment of standardized pharmaceutical quality data elements and terminologies will provide opportunities for FDA and industry to transform PQ/CMC submission data into a readily useable electronic format. As a result, these established data elements and terminologies will improve the efficiency and quality of the drug review process. The Agency is seeking comment on the accuracy, suitability, and appropriateness of these data elements and terminologies for submission of PQ/CMC data. FDA is considering implementing PQ/CMC requirements as a Health Level 7 (HL7) Structured Product Labeling (SPL) document. The proposed data elements and terminologies can be obtained on <https://www.regulations.gov> in Docket No. FDA-2017-N-2166.

DATES: Submit either electronic or written comments by September 11, 2017. Late, untimely filed comments

will not be considered. Electronic comments must be submitted on or before September 11, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 11, 2017. 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.

ADDRESSES: You may submit comments 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-2017-N-2166 for "Draft Standardization of Pharmaceutical Quality/Chemistry Manufacturing and Control Data Elements and Terminologies; Request

for Comments." Received comments, those filed in a timely manner (see **DATES**), 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:

Norman Schmuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 2526, Silver Spring, MD 20993-0002, 301-796-1454; 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, 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. 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 testing data of pharmaceutical products. PQ/CMC encompasses topics such as drug stability, quality specification, and batch analysis, which are important aspects of drug development. PQ/CMC plays an integral part in the regulatory review process and life cycle management of pharmaceutical products. The standardization of PQ/CMC data elements and terminologies will facilitate the Agency's transition to an 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 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), which authorized the Agency to require certain submissions to be 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 harmonized language for submission content, allowing reviewers to query the data, and, in general, contributing to a more efficient and effective regulatory decision-making process by creating a standardized data dictionary.

After receiving comments, the Agency will consider future actions on the standardization of PQ/CMC data elements and terminologies for electronic submissions.

II. Electronic Access

Persons with access to the Internet may obtain the proposed data elements and terminologies at <https://www.regulations.gov>.

Dated: July 5, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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