• The ability of TJC to take into account the capacities of suppliers located in a rural area.

• The comparison of TJC's Medicare HIT accreditation program standards to our current Medicare HIT CfCs.

• A documentation review of TJC's survey process to—

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HITs.

++ Evaluate TJC's procedures for monitoring HITs it has found to be out of compliance with TJC's program requirements.

++ Assess TJC's ability to report deficiencies to the surveyed HIT and respond to the HIT's plan of correction in a timely manner.

++ Establish TJC's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies for surveys being unannounced.

++ TJC's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain TJC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1834(u)(5) of the Act, the July 16, 2019 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CfCs for HIT. No comments were received in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's HIT accreditation requirements and survey process with the Medicare CfCs of 42 CFR part 486, and the survey and certification process requirements of part 488. Our review and evaluation of TJC's HIT application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TJC has completed revising its standards and certification processes to meet the conditions at:

• § 486.520 (b), to address the requirement that the plan of care must be established by a physician prescribing the type, amount and duration for HIT.

• § 486.520 (c), to address the requirement that the plan of care must be periodically reviewed by the physician.

• § 486.525 (a), to address the requirement that the HIT suppliers to be available 7 days a week, 24 hours a day.

• § 486.525 (a)(1), to address the requirement of all professional services, including nursing services, to be available to the home infusion patient.

• § 486.525 (a)(2), to address the requirement for patient education and training to be available for patients on a 7 day a week, 24 hour a day basis.

• § 486.525 (a)(3), to address the requirement of remote monitoring for the provision of HIT.

• § 488.1010 (a)(6)(ii), to ensure surveyors are educated on TJC survey policies and survey process for patient and record selection.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that TJC's requirements for HITs meet or exceed our requirements. Therefore, we approve TJC as a national accreditation organization for HITs that request participation in the Medicare program, effective December 15, 2019 through December 15, 2023.

IV. Collection of Information Requirements

This document does not impose information collection and requirements, that is, reporting, recordkeeping or third party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Dated: December 2, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–26954 Filed 12–13–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0529]

Qualification Process for Drug Development Tools; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) are announcing the availability of a draft guidance for industry and FDA staff entitled ''Qualification Process for Drug Development Tools.'' Under the 21st Century Cures Act (Cures Act), enacted on December 13, 2016, a new section was added to the Federal Food, Drug, and Cosmetic Act (FD&C Act), which defined a three-stage qualification process for drug development tools (DDTs). This guidance meets the Cures Act's mandate to issue guidance on this qualification process and related Prescription Drug User Fee Act (PDUFA) VI commitments. It elaborates on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other DDTs, and the draft guidance of the same name issued January 7, 2014, is withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by February 14, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2010–D–0529 for ''Qualification Process for Drug Development Tools.'' 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.'' CDER and CBER 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 the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), 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 (CBER), 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: Chris Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002; 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

CDER and CBER are announcing the availability of a draft guidance for industry and FDA staff entitled ''Qualification Process for Drug Development Tools.'' Passed into law in December 2016, the Cures Act codified, in new section 507 of the FD&C Act (21 U.S.C. 357), a new statutory process for DDT qualification and added transparency provisions for information related to qualification submissions through which there is enhanced ability to share knowledge and engage with biomedical research consortia. In addition, Congress directed CDER and CBER to establish a taxonomy for the classification of biomarkers (and related scientific concepts) for use in drug (including biological product) development. CDER and CBER convened a public meeting on December 11, 2018, both to solicit public input about implementing the new qualification process under section 507 and about the Biomarkers, EndpointS, and other Tools (BEST) glossary as the taxonomy for classifying types of DDTs, including biomarkers. CDER and CBER are issuing this draft guidance to implement the 507 qualification process, meeting Cures Act mandates and related PDUFA VI commitments.

DDTs are methods, materials, or measures that can aid drug development and regulatory review. Qualification means that a DDT and its proposed context of use can be relied upon to have a specific interpretation and application in drug development and regulatory review. Qualified DDTs can accelerate the integration of innovation, clinical knowledge, and scientific advances, thereby expediting drug development and aiding the regulatory review of applications.

Although the DDT qualification process is voluntary, requestors who seek qualification under section 507 must follow the three-stage process described in the Cures Act. This consists of the following stages: The Letter of Intent, the Qualification Plan, and the Full Qualification Package. These stages are discussed in detail in section III of the draft guidance.

The Cures Act includes transparency provisions that require CDER and CBER to make information with respect to qualification submissions publicly available. A description of information that is made public on the Agency's website is provided in section II of the draft guidance.

CDER and CBER convened a public meeting on December 11, 2018, made available a discussion guide on the implementation of the new section 507 qualification process, and identified the taxonomy (the BEST glossary) for classifying types of DDTs. CDER and CBER have considered public comments made during the meeting and submitted to the docket in developing this draft guidance. This guidance meets the Cures Act's mandate to issue guidance on the section 507 qualification process and related PDUFA VI commitments. This guidance does not address evidentiary standards or performance criteria for purposes of DDT qualification. It also does not address the qualification of medical device development tools or the programs under the Center for Devices and

Radiological Health oversight, which are not addressed in section 507.

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 ''Qualification Process for Drug Development Tools.'' 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 contains information collection that is 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 information collection has been approved under OMB control numbers 0910–0001 and 0910–0014.

III. Electronic Access

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

Dated: December 11, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26994 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of vouchers as well as the approval of products redeeming a voucher. FDA has determined that BEOVU (brolucizumab-dbll), approved October 7, 2019, meets the redemption criteria.

FOR FURTHER INFORMATION CONTACT: Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9858, email: *althea.cuff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that BEOVU (brolucizumab-dbll), approved October 7, 2019, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about BEOVU (brolucizumab-dbll), approved October 7, 2019, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: December 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27054 Filed 12–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by January 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Obtaining Information to Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities''. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

OMB Control Number 0910–NEW

This information collection supports Agency-sponsored research. Drug compounding is generally the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. Since compounded drugs are subject to a lower regulatory standard than approved drugs, Federal law places conditions on compounding that are designed to protect the public health.

The Drug Quality and Security Act of 2013 created ''outsourcing facilities''—a new industry sector of drug compounders held to higher quality standards to protect patient health. Outsourcing facilities are intended to offer a more reliable supply of