public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written Public Comment: Written comments must be received on or before September 2, 2022.

Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment during the September 1–2, 2022, ACIP meeting must submit a request at *https://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m. EDT, August 30, 2022, according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals by email on August 31, 2022, regarding their request to speak. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to three minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2022–18734 Filed 8–25–22; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) 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 award of the priority review voucher. FDA has determined that ZYNTEGLO (betibeglogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, 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: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that ZYNTEGLO (betibeglogene autotemcel), manufactured by bluebird bio, Inc., meets the criteria for a priority review voucher. ZYNTEGLO is indicated for the treatment of adult and pediatric patients with ß-thalassemia who require regular red blood cell transfusions.

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/industry/developing-products-rare-diseases-conditions/rare-pediatric-disease-rpd-designation-and-voucher-programs.* For further information about ZYNTEGLO, go to the Center for Biologics Evaluation and Research's Approved Cellular and Gene Therapy Products website at *https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products.*

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18519 Filed 8–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0093]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Review Transparency and Communication for New Molecular Entity New Drug Applications and Original Biologics License Applications in Prescription Drug User Fee Submissions

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.

DATES: Submit written comments (including recommendations) on the collection of information by September 28, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0746. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three

White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Review Transparency and Communication for New Molecular Entity New Drug Applications (NME NDA) and Original Biologics License Applications (BLAs) in Prescription Drug User Fee Submissions

OMB Control Number 0910–0746—Revision

This information collection supports the evaluation of certain performance goals and procedures set forth in what is known as FDA's ''goals letter'' or ''commitment letter'' under the seventh authorization of the Prescription Drug User Fee Act (PDUFA VII). The goals letter is the result of Agency, industry, and public input, as Congressionally mandated under the applicable statutes. The document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027'' (PDUFA VII Commitment Letter) represents current performance goals agreed to by FDA in support of these respective programs. The document is available at: *https://www.fda.gov/media/151712/download.*

To implement certain performance goals, we established a review program (the Program) to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products that we review. The Program goals are intended to increase the efficiency and effectiveness of the first review cycle process and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the extension of the Program is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals.

Based on sponsors' responses and other data, on December 2, 2020, we published an interim report that is available on FDA's website at *https://www.fda.gov/media/144130/download.* We learned that review teams have been effective in enhancing transparency and communication, with milestone meetings also enhancing the predictability of the review process. We have also adapted certain good practices, including providing pre-submission advice and templates; allocating time for applicant-identified discussion topics in late-cycle meetings where feasible; and recommending request response times of greater than 2 days for applicants with a global presence.

We are revising the information collection to continue the Program and these assessments under the ''PDUFA VII Commitment Letter''. The goals letter includes the procedures, and commitments that apply to aspects of the human drug review program that are important for facilitating timely access to safe, effective, and innovative new medicines for patients. Several of these commitments aim to continue to enhance communication between FDA and sponsors during application review. FDA and sponsors interact in a variety of ways throughout application review. One such way is via a communication, called an information request (IR), sent to an applicant as the discipline review occurs. FDA uses IRs to request further information or clarification that is needed or would be helpful to allow completion of the discipline review. IRs may be in the form of letters, emails, or Faxes.

FDA uses product quality IRs to request further information or clarification needed for FDA's assessment of identity, strength, quality, purity, sterility/microbial controls, or potency of drug substances or drug products. Ensuring that patients can have confidence in the safety and effectiveness of their medications is a longstanding priority for FDA. The Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) have worked to address this priority, in part, by performing Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) reviews for CDER- and CBER-regulated products. It is during these reviews that CDER or CBER may issue a product quality, or CMC, IR. IRs from both CDER and CBER are expected to follow Four-Part Harmony in which reviewers are expected to communicate: (1) what was provided, (2) what is the issue or deficiency, (3) what is needed, and (4) why it is needed. The PDUFA VII Commitment Letter includes commitments for FDA to update and conduct training on existing policies and procedures (Manual of Policies and Procedures and Standard Operating Procedures and Policies) based on the four essential components.

FDA is committed to assessing current practices of CDER, CBER, and sponsors in communicating through product quality IRs during application review and effectiveness of Four-Part Harmony. We will contract with an independent third party to conduct assessments intended to identify best practices and areas of improvement in communications between FDA review staff and sponsors through product quality IRs. To accomplish these goals, the contractor will separately engage both FDA staff and sponsors through contractor-led interviews. Given the volume of IRs and IR amendments, these interviews will focus on a sample of applications and their associated IRs. The contractor may also choose to leverage web-based surveys, in addition to interviews, to accomplish the goals of the assessment. The contractor will anonymize and aggregate sponsor and FDA responses before including them in an assessment report, which is required by the PDUFA VII Commitment Letter. FDA will publish the report on FDA's website and in the **Federal Register,** for public comment.

This assessment, utilizing information collected through surveys and interviews with FDA and original NDA and BLA sponsors, will be of great interest to FDA's stakeholders, including the regulated industry. Equally important, the assessment will be critical in helping FDA understand sponsor perspectives on what is working well, ongoing challenges and pain points, lessons learned, and opportunities for improvement.

Per the commitment letter, FDA will select a contractor to design a sampling method, in accordance with the requirements in the statement of work, for identifying applications to be included in the assessment. The contractor will also prepare a protocol and script for scheduling and conducting interviews with sponsors associated with the sample applications. If the contractor determines a survey to be necessary, they will develop a web-based survey to deploy. The protocol will ensure that the contractor schedules and conducts interviews and deploys any survey in a timely, consistent manner using good interview and survey practices. The interview script will include open-ended questions aimed at obtaining a thorough understanding of applicants' experiences and insights relevant to product quality IRs associated with their application under the Program. If deployed, the survey would include closed and/or open-ended questions with the same purpose.

The contractor will analyze interview (and survey, if deployed) responses to identify challenges with Four-Part Harmony and best practices for

communication via product quality IRs. The contractor will also use the interview (and survey, if deployed) data to consider trends across IRs, compare IRs before and after implementation of Four-Part Harmony, and add context to the contractor's review of the sample IRs, as well as any other data collected. The contractor will synthesize and interpret the results to develop a set of findings and recommendations for the Program to be included in a final assessment report. In turn, FDA will use the independent assessment findings and recommendations to:

- determine the success of Four-Part Harmony in improving communications via product quality IRs;
- determine whether and how to refine implementation of Four-Part Harmony during the remainder of PDUFA VII;
- demonstrate compliance with the commitment to conduct the independent assessments
- and publish them for public comment; and
- share information about the Program with the regulated community, the public health community, Congress, and the general public.

In the **Federal Register** of March 21, 2022 (87 FR 16006), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received; however, we have slightly increased the estimate from our 60-day notice to fully align with planned program goals.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Surveys	120 (one to three per application).	1	120	0.25 (15 minutes)	30
Interviews	120 (one to three per application).	1	120	1.5	180
Total					210

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We plan interviews with up to three sponsor representatives per each application in each interview under the Program. Sponsors will participate in interviews via teleconference. In addition, if the contractor decides to conduct a survey, sponsors will respond to surveys (one survey response per individual) by completing a fillable form online. We estimate that 120 applicant representatives will expend approximately 15 minutes to complete a survey, for a total of 30 annual burden hours. We further estimate that up to 120 applicant representatives (up to three sponsor representatives for each of up to 40 applications) will participate in the interviews each year and that each interview will last approximately 90 minutes, for a total of 180 burden hours. There will be no recordkeeping or third-party disclosure burdens for this information collection.

Dated: August 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–18546 Filed 8–26–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1503]

Q2(R2) Validation of Analytical Procedures and Q14 Analytical Procedure Development; International Council for Harmonisation; Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of two draft guidances for industry entitled ''Q2(R2) Validation of Analytical Procedures'' and ''Q14 Analytical Procedure Development.'' These draft guidances were prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), formerly the International Conference on Harmonisation. These draft guidances harmonize scientific approaches for analytical procedure development and include validation of a wider range of analytical techniques. The draft guidances are intended to facilitate regulatory evaluations and facilitate potential flexibility in postapproval change management of analytical procedures. The draft Q2(R2) guidance revises the ICH guidance for industry ''Q2(R1) Validation of Analytical Procedures: Text and Methodology'' published in November 2005.

DATES: Submit either electronic or written comments on the draft guidance by September 28, 2022 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.*