CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219293Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

IND 144071

MEETING PRELIMINARY COMMENTS

Slayback Pharma LLC
Attention: Praveen Subbappa
Senior Director
301 Carnegie Center, Suite 303
Princeton, NJ 08540

Dear Mr. Subbappa:[1]

Please refer to your pre-investigational new drug application (PIND) file for Nilotinib Tablets, 71 mg and 95 mg.

We also refer to your September 12, 2022, correspondence, received September 12, 2022, requesting a meeting to discuss the proposed contents and format of a New Drug Application (NDA).

Our preliminary responses to your meeting questions are enclosed.

You should provide, to the Regulatory Project Manager, a hardcopy or electronic version of any materials (i.e., slides or handouts) to be presented and/or discussed at the meeting.

In accordance with FDA policy, you should not make audio or visual recordings of the discussion at this meeting. Consistent with 21 CFR 10.65(e), the official record of this meeting will be the FDA-generated minutes.

If you have any questions, please contact me at (301) 796-2927.

Sincerely,

{See appended electronic signature page}

Tawanna Stokes
Regulatory Information Specialist
Hematologic Malignances I
Division of Regulatory Operations for Oncologic Diseases
Office of Regulatory Operations
Center for Drug Evaluation and Research

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

ENCLOSURE:
Preliminary Meeting Comments

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

PRELIMINARY MEETING COMMENTS

Meeting Type: Type B
Meeting Category: Pre-NDA

Meeting Date and Time: November 7, 2022, 3:30 PM
Meeting Location: Virtual (Video Conference)

Application Number: PIND 144071
Product Name: Nilotinib Tablets, 71 mg and 95 mg
Indication: Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase; and Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib
Sponsor Name: Slayback Pharma LLC
Regulatory Pathway: 505(b)(2) of the Federal Food, Drug, and Cosmetic Act

FDA ATTENDEES (tentative)

Office of Oncologic Diseases (OOD)/Division of Hematologic Malignancies I (DHMI)
R. Angelo de Claro, MD, Division Director
Kelly Norsworthy, MD, Clinical Team Leader and Acting Deputy Director
Joseph Wynne, MD, PhD, Clinical Reviewer

Office of Regulatory Operations (ORO)/Division of Regulatory Operations for Oncologic Diseases/Hematologic Malignancies I
Amy Baird, Chief, Project Management Staff
Tawanna Stokes, BA, Regulatory Information Specialist

Office of Oncologic Diseases (OOD)/Division of Hematology, Oncology, Toxicology
Brenda Gehrke, PhD, Nonclinical Supervisor
Daniela Torres, PhD, Nonclinical Reviewer

Office of Clinical Pharmacology/Division of Cancer Pharmacology I
Ruby Leong, PharmD, Clinical Pharmacology Team Leader
Hongfei Zhang, PhD, Clinical Pharmacology Reviewer

Office of Product Quality/Division of Biopharmaceutics Branch I
Linyi (Kevin) Wei, PhD, Biopharmaceutics Team Leader
Qi Zhang, PhD, Biopharmaceutics Reviewer

Oncology Center for Excellence
Tamy Kim, PharmD, Director for Regulatory Affairs and Regulatory Policy
Jessica Boehmer, MBA, Regulatory Scientist

SPONSOR ATTENDEES
Ajay Singh, CEO, Slayback Pharma
Sumitra Pillai, Head R&D, Slayback Pharma
Praveen Subbappa, Senior Director, R&D, Slayback Pharma
Paras Jain, Senior Director Formulation Development, Slayback Pharma
Sandeep Jain, Senior Manager, Slayback Pharma
Keerthi Priya, Senior Manager, Slayback Pharma
Krishna Mohan L, Manager, Slayback Pharma
Satheesh Balasubramanian, Senior Director Analytical Development, Slayback Pharma
Hanimi Reddy, Director Analytical Development, Slayback Pharma
Bhavani Reddy, Senior Director, Regulatory Affairs, Slayback Pharma,
Mahesh Vangara, Manager, Regulatory Affairs, Slayback Pharma
Josh Mathews, Vice President, Product Innovation & Strategy, Slayback Pharma
(b) (4)

Introduction:
This material consists of our preliminary responses to your questions and any additional comments in preparation for the discussion at the meeting scheduled for November 7, 2022, 3:30 PM, between Slayback Pharma and the Division of Hematologic Malignances I. We are sharing this material to promote a collaborative and successful discussion at the meeting. The meeting minutes will reflect agreements, important issues, and any action items discussed during the meeting and may not be identical to these preliminary comments following substantive discussion at the meeting. If you determine that discussion is needed for only some of the original questions, you have the option of reducing the agenda. Contact the Regulatory Project Manager (RPM) if there are any major changes to your development plan, the purpose of the meeting, or the questions based on our preliminary responses, as we may not be prepared to discuss or reach agreement on such changes at the meeting.

1.0 BACKGROUND

Slayback requested a pre-NDA meeting with the Division to discuss the contents and format of an NDA application in support of their product, Nilotinib Tablets, a proposed 505(b)(2) application with the listed drug NDA 022068 Tasigna. Slayback's product differs from the listed drug, Tasigna, as this has a different salt form of the active moiety (tartrate versus hydrochloride monohydrate) and a different oral dosage form (tablet vs

capsule). Slayback previously held a pre-IND meeting in December 2019, September 2020, May 2021, and a meeting with FDA Clinical Pharmacology Staff in August 2021.

2.0 DISCUSSION

2.1. Regulatory

Question 1: *Does the Agency agree that the proposed NDA organization and structure is acceptable for the Agency's review of an NDA for Nilotinib Tablets?*

FDA Response to Question 1:

The proposed NDA organization and structure appear acceptable for the Agency's review. However, see FDA Responses for Questions 3, 4, 5, and 6.

2.2. Nonclinical Pharmacology and Toxicology

Question 2: *Does the Agency agree to the proposal not to prepare Section 2.6?*

FDA Response to Question 2:

Since there are no new nonclinical studies to be submitted, we agree with the approach to only submit section 2.4 (Nonclinical Overview) to the NDA and not include section 2.6.

2.3. Biopharmaceutics and Clinical Pharmacology

Question 3a: *Does the Agency agree that adequate scientific justification has been provided for the reliance on the safety and efficacy of Tasigna? Specifically, does the Agency agree that:*

a. *The results of Study 010-22 demonstrate acceptable relative bioavailability of Nilotinib Tablets, 95 mg and Tasigna, 200 mg, administered in the fasted state at the respective clinical doses (190 mg and 400 mg)?*

FDA Response to Question 3a:

No. Given the observed higher C_{max} of nilotinib following administration of nilotinib tartrate than Tasigna under fasted state in Study 010-22, we have concerns with expected higher nilotinib exposures at steady-state and QT prolongation risk with nilotinib tartrate. You need to address the QT prolongation risk associated with the observed higher C_{max} of nilotinib tartrate than that of Tasigna. If the exposure with nilotinib tartrate is higher than that of Tasigna, you will need to conduct additional QT assessment.

Question 3b: (b) (4)

FDA Response to Question 3b:

No. (b) (4) You should evaluate 3 dose levels that cover equivalent doses of Tasigna to establish dose proportionality of nilotinib tartrate in a single study or conduct a BE study with your final drug product at each Tasigna dose level (200, 300, and 400 mg). Refer to the discussion under Question 9 in the Type C pre-IND meeting on May 3rd, 2021. In the absence of demonstrating dose proportionality of your drug product, you need to evaluate at least 2 dose levels (i.e., both the high and low doses listed in the proposed product labeling) in the food effect and relative bioavailability studies.

The comparative multimedia dissolution testing should be conducted in three different pH media (b) (4). If the proposed QC dissolution method is not deemed appropriate, additional comparative in vitro dissolution profile data using an adequate method (with supporting profile similarity analyses) may be requested.

Question 4a: *Does the Agency agree that Slayback's Nilotinib Tablets have a reduced food effect such that administration under fasting or modified fasting conditions or following a high-fat meal result in rates and extents of exposure that are within the bounds of the LD?*

a. *On this basis, does the Agency agree that it is appropriate to allow for administration without regard to food in the labeling?*

FDA Response to Question 4a:

(b) (4) You should conduct the food effect study under standard fasting, modified fasting and fed conditions to understand the impact of food on the PK of your drug product. PK analysis should include PK comparison under fed and standard fasting conditions as well as under fed and modified fasting conditions. Refer to the following FDA documents of "Guidance for Industry" for greater details:

a. *Food-Effect Bioavailability and Fed Bioequivalence Studies*
b. *Assessing the Effects of Food on Drugs in INDs and NDAs – Clinical Pharmacology Considerations*

Question 5: *Does the Agency agree to the proposal not to prepare Section 2.7.2?*

FDA Response to Question 5:

No, you should submit Section 2.7.2 Summary of Clinical Pharmacology Studies as part of a future NDA.

2.4. Clinical Safety and Efficacy

Question 6: *Does the Agency agree that it is acceptable not to prepare Section 2.7.3, Section 2.7.4, the ISE, and the ISS?*

FDA Response to Question 6:

No. You should prepare and submit a Summary of Clinical Safety in Section 2.7.4 that includes the pooled safety results from your healthy volunteer studies. However, based on your currently proposed NDA package, we agree that submission of an ISE, ISS, and SCE should not be necessary.

Additional Clinical Comment:

Please submit all study protocols for your completed studies in addition to Clinical Study Reports in your future NDA.

3.0 OTHER IMPORTANT MEETING INFORMATION

PREA REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (codified at section 505B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived or deferred (see section 505B(a)(1)(A) of the FD&C Act). Applications for drugs or biological products for which orphan designation has been granted that otherwise would be subject to the requirements of section 505B(a)(1)(A) are exempt pursuant to section 505B(k)(1) from the PREA requirement to conduct pediatric assessments.

Title V of the FDA Reauthorization Act of 2017 (FDARA) amended the statute to create section 505B(a)(1)(B), which requires that any original marketing application for certain

adult oncology drugs (i.e., those intended for treatment of an adult cancer and with molecular targets that FDA has determined to be substantially relevant to the growth or progression of a pediatric cancer) that are submitted on or after August 18, 2020, contain reports of molecularly targeted pediatric cancer investigations. See link to list of relevant molecular targets below. These molecularly targeted pediatric cancer investigations must be "designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling" (section 505B(a)(3)). Applications for drugs or biological products for which orphan designation has been granted and which are subject to the requirements of section 505B(a)(1)(B), however, will not be exempt from PREA (see section 505B(k)(2)) and will be required to include plans to conduct the molecularly targeted pediatric investigations as required, unless such investigations are waived or deferred.

Under section 505B(e)(2)(A)(i) of the FD&C Act, you must submit an Initial Pediatric Study Plan (iPSP) within 60 days of an End of Phase 2 (EOP2) meeting, or such other time as agreed upon with FDA. (In the absence of an EOP2 meeting, refer to the draft guidance below.) The iPSP must contain an outline of the pediatric assessment(s) or molecularly targeted pediatric cancer investigation(s) that you plan to conduct (including, to the extent practicable study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation; and any previously negotiated pediatric plans with other regulatory authorities. The iPSP should be submitted in PDF and Word format. Failure to include an Agreed iPSP with a marketing application could result in a refuse to file action.

For additional guidance on the timing, content, and submission of the iPSP, including an iPSP Template, please refer to the draft guidance for industry *Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans*.

For the latest version of the molecular target list, please refer to FDA.gov.[2]

FDARA REQUIREMENTS

Sponsors planning to submit original applications on or after August 18, 2020 or sponsors who are uncertain of their submission date may request a meeting with the Oncology Center of Excellence Pediatric Oncology Program to discuss preparation of the sponsor's initial pediatric study plan (iPSP) for a drug/biologic that is intended to treat a serious or life-threatening disease/ condition which includes addressing the amendments to PREA (Sec. 505B of the FD &C Act) for early evaluation in the pediatric population of new drugs directed at a target that the FDA deems substantively relevant to the growth or progression of one or more types of cancer in children. The purpose of

[2] https://www.fda.gov/about-fda/oncology-center-excellence/pediatric-oncology

these meetings will be to discuss the Agency's current thinking about the relevance of a specific target and the specific expectations for early assessment in the pediatric population unless substantive justification for a waiver or deferral can be provided. Meetings requests should be sent to the appropriate review division with the cover letter clearly stating "**MEETING REQUEST FOR PREPARATION OF iPSP MEETING UNDER FDARA.**" These meetings will be scheduled within 30 days of meeting request receipt. The Agency strongly advises the complete meeting package be submitted at the same time as the meeting request. Sponsors should consult the guidance for industry, *Formal Meetings Between the FDA and Sponsors or Applicants*, to ensure open lines of dialogue before and during their drug development process.

In addition, you may contact the OCE Subcommittee of PeRC Regulatory Project Manager by email at OCEPERC@fda.hhs.gov. For further guidance on pediatric product development, please refer to FDA.gov.[3]

PRESCRIBING INFORMATION

In your application, you must submit proposed prescribing information (PI) that conforms to the content and format regulations found at 21 CFR 201.56(a) and (d) and 201.57 including the Pregnancy and Lactation Labeling Rule (PLLR) (for applications submitted on or after June 30, 2015). As you develop your proposed PI, we encourage you to review the labeling review resources on the PLR Requirements for Prescribing Information[4] and Pregnancy and Lactation Labeling Final Rule[5] websites, which include:

- The Final Rule (Physician Labeling Rule) on the content and format of the PI for human drug and biological products.
- The Final Rule (Pregnancy and Lactation Labeling Rule) on the content and format of information related to pregnancy, lactation, and females and males of reproductive potential.
- Regulations and related guidance documents.
- A sample tool illustrating the format for Highlights and Contents, and
- The Selected Requirements for Prescribing Information (SRPI) − a checklist of

[3] https://www.fda.gov/drugs/development-resources/pediatric-and-maternal-health-product-development
[4] https://www.fda.gov/drugs/laws-acts-and-rules/plr-requirements-prescribing-information
[5] https://www.fda.gov/drugs/labeling/pregnancy-and-lactation-labeling-drugs-final-rule

important format items from labeling regulations and guidances.

- FDA's established pharmacologic class (EPC) text phrases for inclusion in the Highlights Indications and Usage heading.

Pursuant to the PLLR, you should include the following information with your application to support the changes in the Pregnancy, Lactation, and Females and Males of Reproductive Potential subsections of labeling. The application should include a review and summary of the available published literature regarding the drug's use in pregnant and lactating women and the effects of the drug on male and female fertility (include search parameters and a copy of each reference publication), a cumulative review and summary of relevant cases reported in your pharmacovigilance database (from the time of product development to present), a summary of drug utilization rates amongst females of reproductive potential (e.g., aged 15 to 44 years) calculated cumulatively since initial approval, and an interim report of an ongoing pregnancy registry or a final report on a closed pregnancy registry. If you believe the information is not applicable, provide justification. Otherwise, this information should be located in Module 1. Refer to the draft guidance for industry *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products – Content and Format*.

Prior to submission of your proposed PI, use the SRPI checklist to ensure conformance with the format items in regulations and guidances.

SUBMISSION FORMAT REQUIREMENTS

The Electronic Common Technical Document (eCTD) is CDER and CBER's standard format for electronic regulatory submissions. The following submission types: **NDA, ANDA, BLA, Master File** (except Type III) and **Commercial INDs** must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit FDA.gov.[6]

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to the FDA and enables the secure submission of regulatory information for review. Submissions less than 10 GB must be submitted via the ESG. For submissions that are greater than 10 GB, refer to the FDA technical specification *Specification for Transmitting Electronic Submissions using eCTD Specifications*. For additional information, see FDA.gov.[7]

MANUFACTURING FACILITIES

To facilitate our inspectional process, we request that you clearly identify *in a single*

[6] http://www.fda.gov/ectd
[7] http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway

location, either on the Form FDA 356h, or an attachment to the form, all manufacturing facilities associated with your application. Include the full corporate name of the facility and address where the manufacturing function is performed, with the FEI number, and specific manufacturing responsibilities for each facility.

Also provide the name and title of an onsite contact person, including their phone number, fax number, and email address. Provide a brief description of the manufacturing operation conducted at each facility, including the type of testing and DMF number (if applicable). Each facility should be ready for GMP inspection at the time of submission.

Consider using a table similar to the one below as an attachment to Form FDA 356h. Indicate under Establishment Information on page 1 of Form FDA 356h that the information is provided in the attachment titled, "Product name, NDA/BLA 012345, Establishment Information for Form 356h."

Site Name	Site Address	Federal Establishment Indicator (FEI) or Registration Number (CFN)	Drug Master File Number (if applicable)	Manufacturing Step(s) or Type of Testing [Establishment function]
(1)				
(2)				

Corresponding names and titles of onsite contact:

Site Name	Site Address	Onsite Contact (Person, Title)	Phone and Fax number	Email address
(1)				
(2)				

To facilitate our facility assessment and inspectional process for your marketing application, we refer you to the instructional supplement for filling out Form FDA 356h[8] and the guidance for industry, *Identification of Manufacturing Establishments in Applications Submitted to CBER and CDER Questions and Answers*[9]. Submit all related manufacturing and testing facilities in eCTD Module 3, including those proposed for

[8] https://www.fda.gov/media/84223/download
[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/identification-manufacturing-establishments-applications-submitted-cber-and-cder-questions-and

commercial production and those used for product and manufacturing process development.

505(b)(2) REGULATORY PATHWAY

The Division recommends that sponsors considering the submission of an application through the 505(b)(2) pathway consult the Agency's regulations at 21 CFR 314.54, and the draft guidance for industry *Applications Covered by Section 505(b)(2)* (October 1999).[10] In addition, FDA has explained the background and applicability of section 505(b)(2) in its October 14, 2003, response to a number of citizen petitions that had challenged the Agency's interpretation of this statutory provision (see Docket FDA-2003-P-0274-0015, available at Regulations.gov.[11]

If you intend to submit a 505(b)(2) application that relies for approval on FDA's finding of safety and/or effectiveness for one or more listed drugs, you must establish that such reliance is scientifically appropriate, and must submit data necessary to support any aspects of the proposed drug product that represent modifications to the listed drug(s). You should establish a "bridge" (e.g., via comparative bioavailability data) between your proposed drug product and each listed drug upon which you propose to rely to demonstrate that such reliance is scientifically justified.

If you intend to rely on literature or other studies for which you have no right of reference but that are necessary for approval, you also must establish that reliance on the studies described in the literature or on the other studies is scientifically appropriate. You should include a copy of such published literature in the 505(b)(2) application and identify any listed drug(s) described in the published literature (e.g. by trade name(s)).

If you intend to rely on the Agency's finding of safety and/or effectiveness for a listed drug(s) or published literature describing a listed drug(s) (which is considered to be reliance on FDA's finding of safety and/or effectiveness for the listed drug(s)), you should identify the listed drug(s) in accordance with the Agency's regulations at 21 CFR 314.54. It should be noted that 21 CFR 314.54 requires identification of the "listed drug for which FDA has made a finding of safety and effectiveness," and thus an applicant may only rely upon a listed drug that was approved in an NDA under section 505(c) of the FD&C Act. The regulatory requirements for a 505(b)(2) application (including, but not limited to, an appropriate patent certification or statement) apply to each listed drug upon which a sponsor relies.

If FDA has approved one or more pharmaceutically equivalent products in one or more NDA(s) before the date of submission of the original 505(b)(2) application, you must identify one such pharmaceutically equivalent product as a listed drug (or an additional

[10] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.
[11] http://www.regulations.gov

listed drug) relied upon (see 21 CFR 314.50(i)(1)(i)(C), 314.54, and 314.125(b)(19); see also 21 CFR 314.101(d)(9)). If you identify a listed drug solely to comply with this regulatory requirement, you must provide an appropriate patent certification or statement for any patents that are listed in the Orange Book for the pharmaceutically equivalent product, but you are not required to establish a "bridge" to justify the scientific appropriateness of reliance on the pharmaceutically equivalent product if it is scientifically unnecessary to support approval.

If you propose to rely on FDA's finding of safety and/or effectiveness for a listed drug that has been discontinued from marketing, the acceptability of this approach will be contingent on FDA's consideration of whether the drug was discontinued for reasons of safety or effectiveness.

We encourage you to identify each section of your proposed 505(b)(2) application that is supported by reliance on FDA's finding of safety and/or effectiveness for a listed drug(s) or on published literature (see table below). In your 505(b)(2) application, we encourage you to clearly identify (for each section of the application, including the labeling): (1) the information for the proposed drug product that is provided by reliance on FDA's finding of safety and/or effectiveness for the listed drug or by reliance on published literature; (2) the "bridge" that supports the scientific appropriateness of such reliance; and (3) the specific name (e.g., proprietary name) of each listed drug named in any published literature on which your marketing application relies for approval. If you are proposing to rely on published literature, include copies of the article(s) in your submission.

In addition to identifying the source of supporting information in your annotated labeling, we encourage you to include in your marketing application a summary of the information that supports the application in a table similar to the one below.

List the information essential to the approval of the proposed drug that is provided by reliance on the FDA's previous finding of safety and effectiveness for a listed drug or by reliance on published literature	
Source of information (e.g., published literature, name of listed drug)	**Information Provided (e.g., specific sections of the 505(b)(2) application or labeling)**
(1) Example: Published literature	*Nonclinical toxicology*
(2) Example: NDA XXXXXX "TRADENAME"	*Previous finding of effectiveness for indication A*
(3) Example: NDA YYYYYY "TRADENAME"	*Previous finding of safety for Carcinogenicity, labeling section B*

(4)	

Please be advised that circumstances could change that would render a 505(b)(2) application for this product no longer appropriate. For example, if a pharmaceutically equivalent product were approved before your application is submitted, such that your proposed product would be a "duplicate" of a listed drug and eligible for approval under section 505(j) of the FD&C Act, then it is FDA's policy to refuse to file your application as a 505(b)(2) application (21 CFR 314.101(d)(9)). In such a case, the appropriate submission would be an Abbreviated New Drug Application (ANDA) that cites the duplicate product as the reference listed drug.

ONCOLOGY PILOT PROJECTS

The FDA Oncology Center of Excellence (OCE) is conducting two pilot projects, the Real-Time Oncology Review (RTOR) and the Assessment Aid. RTOR is a pilot review process allowing interactive engagement with the applicant so that review and analysis of data may commence prior to full supplemental NDA/BLA submission. Assessment Aid is a voluntary submission from the applicant to facilitate FDA's assessment of the NDA/BLA application (original or supplemental). An applicant can communicate interest in participating in these pilot programs to the FDA review division by sending a notification to the Regulatory Project Manager when the top-line results of a pivotal trial are available or at the pre-sNDA/sBLA meeting. Those applicants who do not wish to participate in the pilot programs will follow the usual submission process with no impact on review timelines or benefit-risk decisions. More information on these pilot programs, including eligibility criteria and timelines, can be found at the following FDA websites:

- RTOR[12]: In general, the data submission should be fully CDISC-compliant to facilitate efficient review.

- Assessment Aid[13]

[12] https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program
[13] https://www.fda.gov/about-fda/oncology-center-excellence/assessment-aid-pilot-project

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

AMY C BAIRD
11/01/2022 02:07:35 PM
Signing on behalf of Tawanna Stokes