FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: United States of America	**Agency Name:** US Food and Drug Administration	
Name of FRP: Project Orbis		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: 9/17/2019		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☒	☒	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	Before the marketing authorisation submission
Does the agency provide assistance/advice to the sponsor?	Yes- For any product type
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	Project Orbis is for oncology products; supplemental oncology approvals (new indications for previously approved therapies).
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	Click here to enter text.
Total target (agency) time for assessment (calendar days)	Click here to enter text.
Total target (company) time for responses to agency questions (If stated)	Click here to enter text.

Select one of the following (* see definitions at end of document)

Is this a verification review (a recognition pathway)?*	**Is this an abridged* review (selected dossier portions)? (a reliance pathway)?***	**Is this a full* review of all parts of the dossier?**
☐	☐	☒

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Project Orbis is a collaborative review process, allowing simultaneous decisions in the countries involved.
How many reference agency decisions are required?	The three regulatory agencies collaboratively review the application, allowing for simultaneous decisions in all three countries. The aim of the collaborative review is to identify any regulatory divergence across the review teams. *Project Orbis is a US FDA Accelerated Approval; Health Canada uses its conditional approval with conditions and TGA uses its provisional approval with conditions of registration.
Does this FRP require submission of	Not applicable

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Assessment Reports from prior decisions?	
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Not applicable
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable.
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	The U.S. Food and Drug Administration (FDA), the Australian Therapeutic Goods Administration (TGA), Health Canada (HC), Singapore's Health Sciences Authority (HSA) and Swissmedic. Other countries may be involved in future application reviews.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Click here to enter text.
How are queries to the companies sent?	Choose an item.
Are external reviewers (e.g. non-agency) involved in the assessment?	Yes- always
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	Choose an item.
Any other details you wish to provide?	- Project Orbis is an initiative of the U.S. Food and Drug Administration (FDA) Oncology Center of Excellence. Project Orbis brings together regulators from multiple countries to review cancer drugs at the same time so that patients can receive earlier access to needed treatments. - Collaboration among international regulators may allow patients with cancer to receive earlier access to products in other countries where there may be significant delays in regulatory submissions, regardless of whether the product has received FDA approval. - Pivotal clinical trials in oncology are commonly conducted internationally and these global trials are increasingly important for investigating the safety and effectiveness of cancer drugs for approval in the United States. Future drug development may benefit by establishing a greater uniformity of new global standards of treatment, leading to the optimal design of these important trials. - In 2004, FDA's Office of Hematology and Oncology Products (OHOP) began holding regular

	teleconferences under a confidentiality agreement with other regulatory agencies to allow for exchange of information and collaboration on specific topics related to applications under review. Currently, OHOP holds a monthly teleconference with Australia's Therapeutic Goods Administration, Health Canada, the European Medicines Agency, Japan's Pharmaceuticals and Medical Devices Agency, and Switzerland's Swissmedic. In addition, FDA and China's National Medical Products Administration have initiated a quarterly meeting to discuss non-product specific regulatory issues facing worldwide drug development. - FDA and the other agencies will discuss the possibility of collaborating on NDA or BLA reviews for oncology products, but the process may be more complex due to proprietary information involved.
Date of this update	19 APRIL 2020
References	1. International collaboration among Canadian, U.S. and Australian regulators leads to new options for the treatment of cancer. https://www.canada.ca/en/health-canada/news/2019/12/international-collaboration-among-canadian-us-and-australian-regulators-leads-to-new-options-for-the-treatment-of-cancer.html Accessed on 19 April 2020. 2. Project Orbis. https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis Accessed on 19 April 2020. 3. FDA approves first new drug under Project Orbis. https://www.raps.org/news-and-articles/news-articles/2020/4/fda-approves-first-new-drug-under-project-orbis Accessed on 19 April 2020. 4. PROJECT ORBIS: NEW COLLABORATIVE PROGRAM ALLOWS FOR CONCURRENT DRUG APPROVALS IN PARTICIPATING COUNTRIES. https://www.wepclinical.com/project-orbis-new-collaborative-program-allows-for-concurrent-drug-approvals-in-participating-countries/ Accessed on 19 April 2020. 5. Swissmedic participates in FDA Project Orbis. Accessed on 19 April 2020.

*Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent. This may form part of a reliance or recognition pathway.