FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org Country and FRP Information Input Form		
Country: United States of America	**Agency Name:** United States Food and Drug Administration (USFDA)	
Name of FRP: FDA CPP for Unapproved Products		
Is this FRP Proposed or Active? Active		
Date FRP was officially enacted: Click here to enter a date.		
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?	At the time of the 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	Each application entered must be for: • A single drug product • A single dosage form (e.g., capsules) • A single amount/dose (e.g., 5 mg) • A single finished dose manufacturer • Up to MAXIMUM of fifteen (15) countries
Must the product address an unmet medical need or serious condition?	Negotiable
If a fee is required, what is the amount (in US$ equivalent)	CPP Fee Schedule: • First Certificate (original) - $175.00 • Second Certificate - $90.00 • Third and subsequent certificates - $40.00
Total target (agency) time for assessment (calendar days)	CPPs are normally issued within twenty (20) government working days of application receipt. Certification may not be issued 1. Returned with a letter requesting additional information or missing information required in the CPP application 2. Rejected: manufacturing facility status concerns (e.g. a violative facility inspectional status in FDA systems) 3. Denied: drug is not in compliance with applicable regulation (e.g. misbranding not covered by an exemption)
Total target (company) time for responses to agency questions (If stated)	If this office RETURNS your application to you due to discrepancies, you will have 3 business days to resolve and resubmit your application in CDEReCATs. The return notification will be sent via email. If you do not resolve discrepancies within 3 business days, your application will be

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	cancelled.

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?	No, this is not a reliance or recognition pathway.
How many reference agency decisions are required?	Not applicable.
Does this FRP require submission of Assessment Reports from prior decisions?	Not applicable
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?	Have the following information available before applying for CPP: • FEI numbers for all manufacturing facilities • FDA product listing number (NDC number) • Firm Tax ID code or EIN number Have the following information available via PDF for upload before applying for CPP: • Legible Color Labels of drug item • Return Postage label (USP or FEDEX) • Drug Composition/Formulation (if required) • Any Other Attachment required by the importing country (if required)
If this process is through a Regional Regulatory Initiative, which countries participate in this process?	No, this process is not through a Regional Regulatory Initiative.
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Unapproved new human drug can be exported when: • It complies with the laws of the importing country and • It has marketing authorization in Australia, Canada, Israel, Japan, New Zealand, South Africa, or a country in the European Union, European Free Trade Association, or authorized to be marketed in the European Economic Area Approved human drugs exported for unapproved uses: • Investigational use in listed country (see above) • Further processing with a pending market authorization (licensing, listing) *Provision to allow shipping of drugs for tropical diseases or not of significant prevalence in the U.S.

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How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	Choose an item.
Post-authorization study commitments	Always required
For how long is the initial approval or designation valid?	See details Section below
Any other details you wish to provide?	- Can I get a US CPP for a product which is not approved in the US? Yes, in 1996, the Export Reform and Enhancement Act was amended to allow the issue of "export certificates" for products which are not approved in the US. The CPP contains a special comment that the product is not approved. The CPP is issued on standard FDA blue bubble paper with a BLUE ribbon. - Additional required information for CPP: 1. Authorization to Release Information 2. Billing contact 3. Certification Statement 4. Name of Applicant 5. Applicant Contact Information 6. Country of Destination 7. Federal Tax Identification Number (TIN) 8. FDA Marketing Authority 9. Marketing Status in the Exporting Country (U.S.) 10. Status of Applicant 11. Complete Manufacturing Facility Address 12. Facility Registration Number 13. Number of certificates requested 14. U.S. Trade name (the drug product's brand name) 15. Bulk Substance Generic Name 16. Product Identification Statement 17. Product composition - CPP expires twenty four (24) months from the date issued. A new CPP application must be submitted for all certifications. FDA no longer notarizes CPPs.
Date of this update	13 APRIL 2020
References	1. CDER CPP – Unapproved Drug. https://www.fda.gov/media/97627/download Accessed on 13 April 2020. 2. CDER Office of Compliance. Office of Drug Security, Integrity & Recalls. Division of Import Operations & Recalls. Imports Exports Compliance Branch (IECB)

FDA compliance focal point for imports & exports of CDER regulated drugs. https://www.fda.gov/media/91749/download Accessed on 13 April 2020.

3. IFPMA US Certificate of Pharmaceutical Product Questions and Answers (Q&A). https://www.ifpma.org/wp-content/uploads/2018/05/US_CPPs_paper_final_-4May2017.pdf Accessed on 13 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.