US Certificate of Pharmaceutical Product

Questions and Answers (Q&A)

In 1963 the World Health Assembly passed a resolution to ‘examine ways and means of ensuring that drugs exported from a producing country comply with drug control requirement which apply in that country for domestic use.’ Years later the Certificate of Pharmaceutical Product (CPP), which gives countries some assurance from the exporting country regarding the quality, efficacy and safety of the product they are importing, has become one of the most essential legal documents in the registration of medicinal products in over 80 countries. In recent years, with the globalization of the major drug companies, manufacturing may take place anywhere in the world and yet the CPP should still provide details concerning the manufacturer of the dosage form.

However, some countries interpret the WHO Certification Scheme differently to the majority of CPP issuing countries and set certain conditions for issuing CPPs, e.g. manufacture and export from the issuing country to the requesting country, whereas most of the issuing countries provide CPPs for any approved pharmaceutical product.

CPPs are often required from the US. Therefore, this paper gives some practical information on US CPPs. The following questions and answers offer some clarification regarding these essential documents.

**US CPP types**

**Q1: Does the US issue CPPs?**

**A1:** Yes. There are different types of CPPs depending on the approval status, manufacturing and export status of the product. The following CPPs can be issued:

**Standard CPP**

Drug product manufacturing, primary and secondary packaging must all take place in the US. The drug product must be exported from the US to the CPP requesting country. The supply chain approved in the US must be identical to the supply chain proposed in the importing country.

The CPP includes a GMP statement for the manufacturing site. It follows the format of the WHO Certification Scheme and is issued on

1 Please refer to Q6 for non-approved products
standard FDA blue bubble paper with a RED ribbon and it is signed.

**Foreign Manufacturer CPP**

As the name of the CPP already indicates, the drug product is manufactured outside the US. However, primary and secondary packaging and export must take place in the US. The supply chain approved in the US must be identical to the supply chain proposed in the importing country. The Foreign Manufacturer CPP includes a GMP statement for the foreign manufacturing site. The CPP is issued on standard FDA blue bubble paper with a YELLOW ribbon and it is signed.

### Table 1. Overview of CPP Types

<table>
<thead>
<tr>
<th></th>
<th>Standard CPP</th>
<th>Foreign Manufacturer CPP</th>
<th>Foreign Exported CPP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bulk Manufacture</strong></td>
<td>In the US</td>
<td>Outside the US</td>
<td>Outside the US</td>
</tr>
<tr>
<td><strong>Primary and Secondary Packaging</strong></td>
<td>In the US</td>
<td>In the US</td>
<td>Outside the US</td>
</tr>
<tr>
<td><strong>Supply Chain</strong></td>
<td>US supply chain identical to importing country</td>
<td>US supply chain identical to importing country</td>
<td>US supply chain identical to importing country</td>
</tr>
<tr>
<td><strong>Export of finished product</strong></td>
<td>From the US to importing country</td>
<td>From the US to importing country</td>
<td>US not involved</td>
</tr>
<tr>
<td><strong>GMP Statement</strong></td>
<td>Yes, included in CPP for manufacturing site</td>
<td>Yes, included in CPP for manufacturing site</td>
<td>No</td>
</tr>
<tr>
<td><strong>Apostille and / or Legalization</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td><strong>Document Format</strong></td>
<td>Standard FDA blue bubble paper RED ribbon</td>
<td>Standard FDA blue bubble paper YELLOW ribbon</td>
<td>Secure paper, no attachments, no embossed seal, no ribbon</td>
</tr>
</tbody>
</table>
Foreign Exported CPP

Q2: What is a Foreign Exported CPP?

A2: Previously called a pilot US CPP, the Foreign Exported CPP (FE CPP) is the CPP issued for drug products manufactured outside the US, where primary and secondary packaging also takes place outside the US and the product is not exported from the US. The US must have the first and only worldwide approval and the Foreign Exported CPP will only be available until the product is approved by another country’s MoH. The approved supply chain in the US must be identical to the supply chain proposed in the importing country. The Foreign Exported CPP now contains the GMP status of the drug product manufacturing site. There is no marketed or ‘free sale statement’ and no attachments. The CPP is issued on FDA security paper, but does not include any ribbon and it is signed by the CDER approving official. New Applications for an FE CPP may be made electronically via CDEReCATS or by mail (See Reference page for links)

Issuing authority

Q3: Who is the CPP issuing authority in the US?

A3: FDA is the issuing authority, although in the guidelines they plainly state that the current guidance represents only the current thinking of FDA and they are not bound by the guidance. It is made quite plain that alternative approaches may be used, if these conform to the appropriate statutes and regulations. Applicants are encouraged to approach FDA to discuss alternative approaches.

Q4: What information needs to be provided to the issuing authority?

A4: A request form needs to be completed. Details can be taken from the FDA Guidance document on the FDA website.

As in any other country, only the marketing authorization holder can apply for a CPP.

Prerequisites

Q5: Can I get a US CPP if the product is only manufactured and exported from the US?

A5: FDA issues the types of CPPs as described above for human drugs and biologicals, animal drugs and devices for products which may be legally marketed in the US or may be exported from the US, even if these products may not be marketed in the US. In the latter case the CPP contains a notation that the product is not marketed in the US. Single certificates can be issued for products approved with the same NDA number and the same dosage form but with different potencies.

FDA will also issue certificates for products manufactured outside the US. The product must, however, be exported from the US to the importing country (see Table 1).

Q6: Can I get a US CPP for a product which is not approved in the US?

A6: 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.
Q7: What is the difference between a US CPP and an FDA export certificate?

A7: FDA issues a variety of export certificates, of which the Certificate of Pharmaceutical Product (CPP) is one and the only one for pharmaceutical products. The other certificates include Free Sales certificates, Health Certificates for Food/Feed, Non-Clinical Research Use only Certificates, Specified Risk Material Certificates, Certificate to Foreign Government and the Certificate of Exportability; none of these are issued for pharmaceutical products.

Q8: Is it possible to provide the artworks to FDA instead of actual packaging material for US CPP issuance?

A8: Yes, the FDA can accept either PDF or hard copy.

Format

Q9: Does the US CPP follow the WHO guideline/format?

A9: Yes, the US CPP conforms to the format dictated by the WHO certification scheme.

Q10: What are the attachments included by default in any US CPP?

A10: With the exception of the Foreign Exported CPP, where no attachments are possible, the US packaging components are mandatory attachments. Product composition and approved shelf-life constitute optional attachments.

GMP status

Q11: Is the GMP status of the manufacturer declared in the US CPP?

A11: Yes, FDA will not issue a certificate if the manufacturing facilities do not comply with GMP regulations, unless the product is not affected by the specific GMP deficiencies.

Issuance and validity times

Q12: How long does it take to get a US CPP and what does it cost?

A12: FDA will issue a CPP within 20 government working days. A fee will only be charged if the certificate is issued within this specified time. The current fee for a CPP can be found on the FDA website, and it may vary according to the type of certificate requested. Subsequent certificates for the same country are issued at a reduced price.

Q13: How long are the US CPPs valid?

A13: The CPPs issued by FDA expire 24 months after the date of the CPP. An expiry statement is included in the document.

Scope exclusion

Q14: When will FDA not issue a CPP?

A14: FDA will not issue a CPP under certain conditions: if the product does not fulfill the requirements of the Export Reform and Enhancement Act; if the manufacturer has had an enforcement action initiated against them; or if the manufacturer fails to comply with GMP regulations or if the manufacturing facility is not registered with the FDA.
Q15: Does the FDA accept electronic applications for CPP?

A15: The FDA accepts electronic CPP applications via the CDER Export Certification and Tracking System (CDEReCATS). An online Account ID (FURLS) is needed in order to access CDEReCATS. (See Reference page for links.)

**Decision Tree to select the right type of CPP**

- Is the product approved in the US? **NO**
  - Export CPP for unapproved product

- Is the product manufactured in the US? **NO**
  - Is the product packaged and exported from the US? **NO**
    - FOREIGN EXPORTED CPP
  - **YES**
    - FOREIGN MANUFACTURER CPP

- Is the product packaged and exported from the US? **YES**
  - STANDARD CPP
Questions & Answers

Disclaimer

This document is only for descriptive and informational purposes and reflects the most common experience of the IFPMA member companies on 04 May 2017.

National regulatory authority guidelines may be subject to change for further details please consult the corresponding FDA websites.

References

1. WHO Certification Scheme and Certificate of Pharmaceutical Product  

2. FDA Export Reform and Enhancement Act of 1996  
   http://www.fda.gov/regulatoryinformation/legislation/significantamendmentsstothefdact/ucm148005.htm

3. FDA Export Certificates User Fees  

Other Links

FDA Export Certificates – Guidance for Industry  
http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm

Certificate of a Pharmaceutical Product (CPP) Information on FDA website – Links to Examples of Completed Form 3613b  
http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/importsandexportscompliance/ucm348825.htm

FDA Industry Systems/FDA Unified Registration and Listing Systems (FURLS)  
https://www.access.fda.gov/oaarologonFlow.htm?execution=e2s1

CDER Export Certification and Tracking System (CDEReCATS)  
https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ImportsandExportsCompliance/ucm496247.htm

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