Frequently Asked Questions
PLAIRs (Pre-Launch Activities Importation Requests)
Issued July 2013

1. **Can I import an unapproved new drug product to a foreign trade zone (FTZ) and submit a PLAIR?**

   No, you will need to choose one (1) of the two options:

   1) Import into a FTZ
   2) Submit a PLAIR to the following mailbox CDER-OC-PLAIR@fda.hhs.gov

2. **If the sponsor owns the distribution facility, can the sponsor import under the PLAIR program to a distribution facility not identified in the application?**

   No, the distribution facility and warehouse facility owned by the sponsor should be included in the original pending new drug application (NDA); Abbreviated New Drug Application (ANDA) or Biologic License Application (BLA) regulated by the Center for Drug Evaluation and Research (CDER).

3. **Can I submit a PLAIR for a supplement, such as a PAS (Prior Approval Supplement), CBE-30 (Changes Being Effected in 30 days), or CBE-0 (Changes Being Effected?)**

   No, a PLAIR can only be submitted for an original pending application for unapproved finished dosage drug product. It does not apply to approved drug applications with a pending supplement.

4. **Can I submit a PLAIR for a supplement for a new strength?**

   No, a PLAIR can only be submitted for an original pending application for an unapproved finished dosage form drug product.

5. **Can I submit a PLAIR for an API (Active Pharmaceutical Ingredient) or a bulk drug ingredient?**

   No, a PLAIR can only be submitted for an unapproved finished dosage form drug product.

6. **When can we submit a PLAIR amendment and how long does it take to process?**

   A PLAIR amendment can be submitted after the PLAIR has been granted. A PLAIR amendment may take up to 1- 2 business day(s) to process, however, the processing time may be shorter or longer, depending on the number of amendments received by FDA.

7. **Can we import the unapproved finished dosage form drug product into the US prior to obtaining application approval?**

   Yes, you may import unapproved finished dosage form drug product into the US after the PLAIR has been granted and the Division of Import Operations has been notified of the entry number.

8. **Can a PLAIR be granted for the shipment of physician prescription drug samples, products intended for tradeshows or exhibitions?**

   No, the PLAIR program only allows for the importation of an unapproved finished dosage form drug product in preparation for market launch.

9. **Can a firm submit multiple PLAIR submissions for different original applications under one request?**

   No, only one PLAIR submission may be submitted for each original new drug application. Each PLAIR request for an original NDA, ANDA or BLA is handled separately.

10. Can we submit one PLAIR submission for an original new drug application and include multiple product strengths?

Yes, if the multiple strengths are covered under one original drug application.

11. What are some reasons for a denied PLAIR?

A PLAIR may be denied for one or more reasons, including but not limited to:

- PLAIR was submitted earlier than 60 days of expected approval or decision date
- Foreign manufacturer does not have a qualifying facility inspection
- Foreign manufacturer is not within GMP compliance
- Deficiencies noted in the original application

12. How long does it take for a PLAIR submission to be processed?

We estimate that, typically, the PLAIR process will take approximately 10 business days; however, the processing time may be longer or shorter, depending on the number of requests received by FDA and other aspects of the request.

13. Can a distributor, importer, consignee, or carrier submit a PLAIR?

No, only the new drug sponsor/applicant or the foreign sponsor's US agent may submit a PLAIR.