Logistics Services Providers Assure Immediate Order Fulfillment for Manufacturers With Approved PLAIR Requests

Pre-Launch Activities Must Be Completed Prior To Initial Shipment

Pharmaceutical manufacturers rely on Logistics Services Providers including WDSrx to provide healthcare supply chain solutions that assure medications reach their destinations when promised.

Government regulatory authorities including the Federal Food and Drug Administration must approve all medications before they are able to be commercially available.

Under special circumstances, unapproved drugs may be prepared for product launch in advance of their approval when a Pre-Launch Activities Importation Request, known as a PLAIR is submitted to and approved by the FDA.

WDSrx and other logistics services providers play an important role to complete this process.

INITIATING A PLAIR REQUEST

PLAIR submissions are limited to finished dosage forms in their final packaged form for a pending new drug

application (NDA), an abbreviated new drug application (ANDA) and a biologics licensing application (BLA).

After a PLAIR is approved, the importer of the unapproved drug must provide documentation at the port of entry that complies with the PLAIR requirements. When required, experienced customs brokers working with WDSrx guide the product from the port to a nearby secure warehouse facility that complies with 21CFR210/211 cGMP guidelines for prescription drugs.

If the FDA approves the drug within six months of the date of entry, the product is released into the supply chain. After six months have passed without an approval, the conditions are not met and the product is rejected.

PREPARATIONS PRIOR TO FDA APPROVAL

While awaiting FDA approval, WDSrx gathers advance orders from the manufacturer and plans strategy to fulfill them immediately after FDA approval is received. Considerations include the possibility of additional labor requirements, extended hours of operation, alternatives and options to assure prompt pick-up and delivery and assuring sufficient transportation options to accommodate higher volume.

“The successful implementation of a PLAIR request requires involvement from specialists along the full scope of logistics services from customs brokerage and importation, handling and storage of quarantined products, order fulfillment, transportation management and government reporting,” according to WDSrx President Adam Runsdorf.

When the drug application is approved, the PLAIR approval letter must be emailed to the FDA district office for comparison to confirm the product imported under a PLAIR matches the approved application.

CONCLUSION

The unique requirements for manufacturers submitting PLAIR requests demands close coordination with experienced Logistics Services Providers to assure immediate order fulfillment.

Unapproved drug products are kept in a quarantine area prior to receiving FDA approval for the manufacturer PLAIR request.

Immediately upon receipt of FDA approval of a manufacturer PLAIR request, all product back orders are fulfilled so the medication can reach patients as soon as possible.