PLEASE CONTINUE TO SUBMIT THE BELOW INFORMATION FOR A PLAIR UNTIL THE FINAL PLAIR GUIDANCE HAS BEEN PUBLISHED.

The PLAIR request should be submitted only to the email address, CDER-OC-PLAIR@fda.hhs.gov, at least one month before the proposed arrival date of the shipment to allow sufficient time to process the request but no more than 60 days prior to anticipated approval. The PLAIR request should be submitted by the sponsor or the applicant holder on firm's letterhead. Applicant should include in the subject line the application number and drug product name. Before submitting a PLAIR, please ensure that you have the actual quantities you plan to import. We cannot accept PLAIR requests from distributors, consignees, etc…Please keep in mind that the foreign drug product manufacturer must have a satisfactory GMP inspection. The PLAIR program only applies to finished dosage drug products.

The following information should be provided on an electronic compatible file:

(a)The drug product name (trade and established) and how supplied (complete product description).
(b)The name of the CDER Office of New Drugs or Office of Generic Drugs project manager assigned to the pending original application.
(c)The National Drug Code (NDC) number, if assigned.
(d)The name, address, registration number, and telephone number of the foreign manufacturer of the finished dosage form drug product.
(e)The name, address, registration number, and telephone number of the U.S. consignee.
(f)The application number for the finished dosage form drug product that is pending approval by FDA.
(g)The name, address, registration number, and telephone number of the warehouse or the distribution facility controlled by or under contract with the applicant where the finished dosage form drug product in final packaged form will be stored pending approval. This facility should be identified in the pending application.
(h)When a finished dosage form drug product in bulk is imported for minimal further processing, information regarding the facility where minimal further processing activities will occur, including (1) the name and address of the facility, (2) a description of the further processing activities, (3) information about where the unapproved finished dosage form drug product in final packaged form will be stored pending approval, and (4) the registration number. This facility should be identified in the pending application.
(i)A letter signed by an authorized representative of the applicant certifying under 18 U.S.C. 1001 that neither the applicant nor its consignees or distributors will sell, offer for sale, or distribute this drug product in U.S. commerce until FDA approval is effective.

After receipt of this information, we will decide on a case-by-case basis, whether to exercise enforcement discretion to permit entry of the unapproved, finished dosage form

drug product and notify you if the importation request is acceptable (normally within two weeks). Please note that the firm must be registered and once the application is approved the drug must be listed. Once a PLAIR has been granted, you should then provide in advance to DIO (DIOPPLAIR@fda.hhs.gov) the Customs entry number your company is importing under the PLAIR enforcement discretion by email. Also, please note that one import entry (regardless of the quantity, batches or lot numbers offered for imports) will be granted for the initial market launching. Keep in mind that the amount of drug product imported into the US must match with what you stated in the original PLAIR submission. Otherwise, an amended PLAIR should be submitted to CDER-OC-PLAIR@fda.hhs.gov for approval. *However, please do not send an amended PLAIR until it has been granted.*

Please note that Section 505(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 355(a)) prohibits the introduction or delivery for introduction into interstate commerce of a new drug "unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug". The Agency's Center for Drug Evaluation and Research (CDER) and the Division of Import Operations and Policy (DIOP) exercise enforcement discretion to permit certain interstate shipments of unapproved products in finished dosage form by the domestic drug industry to prepare these products for market launch in anticipation of approval. These shipments are being allowed under certain controls and restrictions (e.g., the drug products may only be shipped to the facility identified in a pending NDA or ANDA or to facility owned and controlled by the applicant).

Thanks,

CDER-OC-PLAIR@fda.hhs.gov