

Frequently Asked Questions
Temporary Importation of Lipodox
(Doxorubicin HCL Liposomal Injection)

Q1. Will the temporary importation supply of Sun Pharma Global FZE’s doxorubicin hydrochloride liposome injection (Lipodox) totally alleviate the shortage of doxorubicin hydrochloride liposome injection in the U.S.?

A1. The importing firm plans to have additional supplies of doxorubicin hydrochloride liposome injection over the coming weeks to gradually address U.S. patient needs.

Q2. Is Lipodox the same as Doxil, or a generic of Doxil?

A2. Lipodox is a drug with the same active ingredient, dosage, strength, and route of administration as the FDA-approved drug Doxil, and Lipodox is manufactured in a facility that has been inspected by FDA and found to be in compliance with current good manufacturing practices. Lipodox has not been approved by FDA, and therefore, FDA cannot consider it a “generic” of Doxil. The agency has exercised enforcement discretion for the importation of Lipodox during this critical shortage of Doxil.

Q3. How long will FDA exercise enforcement discretion for the importation of Lipodox?

A3. FDA’s exercise of enforcement discretion for the importation Lipodox is temporary. The agency has exercised enforcement discretion for the importation of Lipodox during this critical shortage of Doxil.

Q4. How often does temporary importation occur?

A4. Temporary importation of foreign drugs is considered only in cases when there is a shortage of an approved US drug that is critical to patients, and the shortage cannot be resolved by manufacturers of the approved US drug in the immediate future. FDA’s exercise of enforcement discretion for foreign drugs is limited to importation and distribution under specified, controlled circumstances by identified firms, such as this instance with regard to Sun Pharma Global FZE and its authorized distributor, Caraco Pharmaceutical Laboratories Ltd. Eight drugs have been temporarily imported in the past two years to address shortages, and four are currently being imported, in addition to doxorubicin hydrochloride liposome injection. The other four drugs currently being imported are listed on FDA's Drug Shortage website and are leucovorin injection, ethiodol injection, thiotepa injection and foscarnet injection.

Q5. How will Lipodox be distributed?

A5. This product is being distributed by Sun Pharma Global FZE and its authorized distributor, Caraco Pharmaceutical Laboratories Ltd, through direct order and a limited number of wholesalers. Additional information on Lipodox can be obtained by calling Sun’s toll free number 1-888-835-2237. For additional information on the product, FDA

has posted The Dear Healthcare Professional Letter on our Drug Shortage web page at: <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM292634.pdf>

Q6. Would the agency consider importation for other critical drug shortages? If so, which ones?

A6. Yes, but temporary importation of foreign drugs is considered only in cases when there is a shortage of an approved US drug that is critical to patients and the shortage cannot be resolved by manufacturers of the approved US drug in the immediate future. In these cases, FDA searches for companies that manufacture drugs that are approved in foreign markets and may help meet critical patient needs in the US. When a firm is identified that is willing and able to import a foreign drug, FDA evaluates the overseas drug to ensure that it is of adequate quality and that the drug does not pose significant risks for US patients. Only then does FDA exercise its enforcement discretion for a firm's temporary importation of an overseas drug into the US market. FDA's exercise of enforcement discretion does not mean that the overseas drug is now FDA approved in the US; instead, temporary importation under FDA's exercise of enforcement discretion helps meet patient needs in the US during a critical shortage. Importation is also not always an option to address shortages of critical drugs because there is not always an overseas firm willing and able to import to help address a shortage.