

FDA to import syphilis drug from France amid shortage

January 11 2024, by Robin Foster



Amid an ongoing shortage of the first-line treatment for syphilis in the



United States, the U.S. Food and Drug Administration will allow the importation of a different syphilis drug from a French drugmaker.

In a <u>letter</u> from Laboratoires Delbert, the Paris-based company said it's working with the FDA to temporarily import 3.5 million units of Extencilline, which is not approved in the United States. The move was <u>approved</u> by the FDA on Wednesday.

Bicillin, a long-acting injectable form of penicillin made by Pfizer that is similar to Extencilline, has been in short supply in the United States since the middle of 2023.

It is the recommended treatment for <u>syphilis</u> in adults and it's the only recommended treatment for <u>pregnant women</u> to prevent syphilis passing from mother to newborn.

The National Coalition of STD Directors applauded the FDA's move.

"The delays in treatment that women have faced because of the shortage has placed them and their families at grave risk during the nation's syphilis crisis," executive director <u>David Harvey</u> said in a <u>statement</u>. "Today, the <u>administration</u> took meaningful action on our ongoing ask they do anything and everything in their power to address the Bicillin L-A shortage and to provide communities with the resources they need to treat patients and solve this <u>public health crisis</u>."

"We hope this is the first step toward seeing a resolution to this shortage and that HHS [U.S. Department of Health and Human Services] and FDA will continue to take steps to ensure that communities never experience a syphilis treatment shortage again," Harvey added.

In October, the coalition joined dozens of other public health groups in urging the Biden administration to address the Bicillin shortage as



syphilis cases jumped across the country, *CNN* reported. The FDA's drug shortages database says the supply problem should ease in the second quarter of 2024.

Syphilis cases have jumped about 74% between 2017 and 2021, while cases of syphilis in newborns increased more than 203%, according to data from the U.S. Centers for Disease Control and Prevention.

Syphilis in infants can be severe, disabling, and even fatal. A single course of penicillin at least a month before delivery nearly always prevents infected mothers from passing the disease to their babies.

More information: Visit the U.S. Centers for Disease Control and Prevention for more on <u>syphilis</u>.

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Citation: FDA to import syphilis drug from France amid shortage (2024, January 11) retrieved 9 May 2024 from https://medicalxpress.com/news/2024-01-fda-import-syphilis-drug-france.html

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