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## **DEPARTMENT OF COMMERCE**

### **Foreign-Trade Zones Board**

**[B-16-2018]**

### **Foreign-Trade Zone (FTZ) 61 – San Juan, Puerto Rico; Notification of Proposed Production Activity, Janssen Ortho LLC (Pharmaceuticals), Gurabo, Puerto Rico**

Janssen Ortho LLC (Janssen) submitted a notification of proposed production activity to the FTZ Board for its facility in Gurabo, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on February 27, 2018.

Janssen already has authority to produce certain pharmaceutical products within Subzone 61N. The current request would add a finished product and a foreign status material/component to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status material/component and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Janssen from customs duty payments on the foreign-status material/component used in export production. On its domestic sales, for the foreign-status material/component noted below and those in the existing scope of authority, Janssen would be able to choose the duty rate during customs entry procedures that applies to Erleada™ (apalutamide 60 mg oral tablets) (duty-free). Janssen would be able to avoid duty on foreign-status components which

becomes scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The material/component sourced from abroad is apalutamide API (duty rate 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is **[INSERT DATE 40 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue, NW, Washington, DC 20230-0002, and in the "Reading Room" section of the Board's website, which is accessible via [www.trade.gov/ftz](http://www.trade.gov/ftz).

For further information, contact Christopher Wedderburn at [Chris.Wedderburn@trade.gov](mailto:Chris.Wedderburn@trade.gov) or (202) 482-1963.

Dated: March 6, 2018.

**Andrew McGilvray,**

*Executive Secretary.*

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