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DEPARTMENT OF COMMERCE
Foreign-Trade Zones Board
[B-44-2019]

Foreign-Trade Zone (FTZ) 7 – Mayaguez, Puerto Rico
Notification of Proposed Production Activity
Patheon Puerto Rico, Inc.
(Pharmaceutical Products)
Manatí, Puerto Rico

The Puerto Rico Industrial Development Company, grantee of FTZ 7, submitted a notification of proposed production activity to the FTZ Board on behalf of Patheon Puerto Rico, Inc. (Patheon), located in Manatí, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on August 2, 2019.

Patheon already has authority to produce certain pharmaceutical products within FTZ 7. The current request would add a finished product and foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components 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 Patheon from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, for the foreign-status materials/components noted below and in the existing scope of authority, Patheon would be able to choose the duty rates during customs entry procedures that apply to empaglifozin and metformin hydrochloride tablets (duty-free). Patheon would be able to avoid duty on foreign-status components

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

The materials/components sourced from abroad include: emapaglifozin – active pharmaceutical ingredient; metformin hydrochloride; copovidone; silica, colloidal anhydrous; magnesium stearate; opadry (coating); and, corn (maize) starch (duty rate ranges from duty-free to 6.5%).

The request indicates that certain materials/components are subject to special duties under Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: ftz@trade.gov. 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 in the "Reading Room" section of the Board's website, which is accessible via www.trade.gov/ftz.

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

Dated: August 7, 2019.

Elizabeth Whiteman,
Acting Executive Secretary.
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