



DEPARTMENT OF COMMERCE
Foreign-Trade Zones Board
[B-13-2017]

Foreign-Trade Zone (FTZ) 7 – Mayaguez, Puerto Rico;
Notification of Proposed Production Activity
Romark Global Pharma, LLC
Subzone 7P
Manatí, Puerto Rico
(Pharmaceuticals)

Romark Global Pharma, LLC (Romark), operator of Subzone 7P, submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 7P, in Manatí, Puerto Rico. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on February 6, 2017.

The Romark facility, currently under construction, will be used to produce finished pharmaceutical products and active ingredients. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Romark from customs duty payments on the foreign-status components used in export production. On its domestic sales, Romark would be able to choose the duty rates during customs entry procedures that apply to Alinia® (nitazoxanide) tablets and oral suspension, nitazoxanide controlled release bilayer tablets, and nitazoxanide (active pharmaceutical ingredient) (duty rates – free and 6.5%) for the foreign-status inputs noted below. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: croscarmellose sodium; microcrystalline cellulose; plastic bottles; container labels; glass bottles; plastic caps; paper board cartons; colloidal silicon dioxide; cotton coil packaging; desiccant bags; dibasic calcium phosphate; hydroxypropyl cellulose; hydroxypropylmethylcellulose; hypromellose; product information paper inserts; magnesium stearate; pregelatinized corn starch; anhydrous citric acid; corn starch; strawberry flavoring with alcohol; sodium carboxymethylcellulose; nitazoxanide; sodium benzoate; sodium citrate dihydrate; sodium starch glycolate; talc; purified water; and, xanthan gum (duty rates range from free to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ 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 FTZ Board's website, which is accessible via www.trade.gov/ftz.

For further information, contact Diane Finver at Diane.Finver@trade.gov or (202) 482-1367.

Dated: February 21, 2017

/s/ Andrew McGilvray

Andrew McGilvray
Executive Secretary

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