U.S. DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board
(Docket 80-2011)

Foreign-Trade Zone 7 – Mayaguez, Puerto Rico
Expansion of Manufacturing Authority
Amgen Manufacturing Limited
(Biotechnology and Healthcare Products)
Juncos, Puerto Rico

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Puerto Rico Industrial Development Company, grantee of FTZ 7, requesting an expansion of the scope of manufacturing authority approved within Subzone 7M, on behalf of Amgen Manufacturing Limited (Amgen) in Juncos, Puerto Rico. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR part 400). It was formally filed on December 15, 2011.

Subzone 7M (2,838 employees, 75 million vial and 38 million syringe capacity) was approved by the Board in 2008 for the manufacture of epogen® (epoetin alfa), neupogen® (filgrastim), aransep® (darbepoetin alfa), enbrel® (etanercept), kineret® (anakinra), and neulasta® (pegfilgrastim) (Board Order 1597, 73 FR 78290-78291, 12-22-2008). The subzone facility (221 acres) is located at Road PR 31 Km. 24.6, in Juncos, Puerto Rico.

The current request involves an expansion of the capacity of the facility to 98 million vials and 50 million syringes as well as the addition of the following new products: sensipar® (cinacalcet), enbrel® (enanercept) with auto injector and denosumab. New components and materials sourced from abroad (representing 1% of the value of the finished product) include: sucrose formulation, sodium citrate, sensipar bulk API, L-glutamine USP, antisera and blood fractions modified immunological products, resin, sunbright polyether, phenyl sepharose, acrylic polymers, auto injector devices, stoppers, plunger rods, partitions, dispenser packs, packing material, vials, filters and syringes (duty rate ranges from duty-free to 35.74¢/kg). The application also requests authority to include a broad range of inputs and finished biotechnology and healthcare products that Amgen may produce under FTZ procedures in the future.

New major activity involving these inputs/products would require review by the FTZ Board. The scope otherwise would remain unchanged.

FTZ procedures could exempt Amgen from customs duty payments on the additional capacity and foreign components used in export production. The company anticipates that some 48 percent of the plant's shipments will be exported. On its domestic sales, Amgen would be able to choose the duty rates during customs entry procedures that apply to sensipar® (cinacalcet), enbrel® (enanercept) with auto injector and denosumab (duty-free) for the foreign inputs noted above. The request indicates that the savings from FTZ procedures help improve the plant's international competitiveness.

In accordance with the Board's regulations, Elizabeth Whiteman of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is ***[insert 60 days from date of publication]***. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to March 7, 2012.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 2111, 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.

For further information, contact Elizabeth Whiteman at Elizabeth.Whiteman@trade.gov or (202) 482-0473.

Dated: December 15, 2011

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Andrew McGilvray
Executive Secretary

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