



DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-44-2025]

Foreign-Trade Zone (FTZ) 189, Notification of Proposed Production Activity; Grand River Aseptic Manufacturing; (Pharmaceutical Products); Caledonia and Grand Rapids, Michigan

Kent-Ottawa-Muskegon Foreign-Trade Zone Authority, grantee of FTZ 189, submitted a notification of proposed production activity to the FTZ Board (the Board) on behalf of Grand River Aseptic Manufacturing (GRAM) for GRAM's facilities in Caledonia and Grand Rapids within Subzone 189H. The notification conforming to the requirements of the Board's regulations (15 CFR 400.22) was received on September 12, 2025.

Pursuant to 15 CFR 400.14(b), FTZ production activity would be limited to the specific foreign-status material(s)/component(s) and specific finished product(s) described in the submitted notification (summarized below) and subsequently authorized by the Board. The benefits that may stem from conducting production activity under FTZ procedures are explained in the background section of the Board's website – accessible via www.trade.gov/ftz.

The proposed finished products are atigotatug - nivolumab 420mg and 360mg/vials (70mg and 60mg/mL) and atigotatug - nivolumab 560mg and 480mg/vials (70mg and 60mg/mL) (duty-free).

The proposed foreign-status material is nivolumab (180mg/mL) active pharmaceutical ingredient (duty-free).

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 "Online FTZ Information System" section of the Board's website.

For further information, contact Christopher Wedderburn at
Chris.Wedderburn@trade.gov.

Dated: September 15, 2025.

Elizabeth Whiteman,
Executive Secretary.

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