

Dear SwiftDox Team,

Thank you for your response. We would like to provide further clarification regarding the two products included in our Certificate of Free Sale application and respectfully request that the application be reconsidered based on the nature of the products and their current distribution channels.

1. Enterex DBT

Enterex DBT is manufactured and commercially sold in the United States under the name **Enterex Diabetic**. The same product is exported to Venezuela under the name **Enterex DBT** solely to comply with regulatory and labeling requirements applicable in the destination country.

The product, formulation, and manufacturing process are the same; only the commercial name differs.

We are able to provide a recent U.S. sales invoice demonstrating the sale of **Enterex Diabetic** to a U.S. customer, which should establish the U.S. commercial availability of the product.

2. Enterex Total

Enterex Total is **manufactured in the United States; however, it is currently manufactured exclusively for export markets and is no longer commercially sold in the United States**. Consequently, there is no recent U.S. sales invoice for this product to provide, as there are no current domestic sales.

We understand the requirement for an invoice showing a sale to a U.S. consumer or business. However, in the particular case of Enterex Total, a U.S. sales invoice is not available because the product's current commercial distribution is exclusively through export channels.

We therefore are attaching attesting source of Manufacturing for **Enterex Total Vanilla, Strawberry and Chocolate 237ml and Enterex DBT Vanilla and Strawberry** as a legitimate products manufactured for commercial export

Since the purpose of the Certificate of Free Sale is to support the registration and export of these products to Venezuela, we would appreciate your consideration of the actual commercial circumstances of Enterex Total rather than requiring documentation that, by the nature of its current distribution, does not exist.



Please advise us whether the U.S. invoice for Enterex Diabetic, together with alternative documentation supporting the U.S. manufacture and export status of Enterex Total, would be acceptable for reconsideration of our application.

Thank you for your attention to this matter. We look forward to your guidance and hope we can find a suitable way to proceed with the issuance of the Certificate of Free Sale.

Best regards,

A handwritten signature in black ink, appearing to read "Ileana Yanes", written over the printed name and title.

Ileana Yanes

Vice-President Regulatory affairs