Lactose IID Statement

Product group:	Lactose and Inhalation
Brand name:	SuperTab®, Pharmatose®, Respitose®,Lactochem®, Lactohale®, Lactopress®
Product description:	Lactose monohydrate, Anhydrous Lactose
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Dear Customer,

SuperTab®, Lactochem®, Lactohale®, Lactopress®, Pharmatose® and Respitose® are brand names for DFE's pharmaceutical grade lactose. It complies with the requirements of the current versions of the USP-NF, Ph. Eur., JP and, where applicable, ChP monographs, as specified in the corresponding certificate of analysis.

Lactose is a widely used ingredient. Its inclusion in FDA's Inactive Ingredient Database (IID) supports its established use in approved drug products, as exemplified by the number of applications where lactose is used as a filler/binder. Furthermore, lactose is permitted for food use in the United States and is described in 21 CFR 168.122.

Limits in the IID are listed for excipients as described by applicants "as it is" in their filings e.g. anhydrous lactose, monohydrate or only lactose. After administration, both lactose monohydrate and anhydrous lactose dissolve and have exactly the same biological properties.

This statement substitutes all previous versions issued for the brand names mentioned above.
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

With kindest regards,

Name : Lorina Bisharat
Job title : Regulatory Affairs Manager
Signature :

This document is controlled by a validated, electronic system and is valid without signature.
The above facsimile signature is only for display.

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