BSE/TSE - Statement

Information for USA

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

Herewith we certify that:

- Processing of milk to pharmaceutical grade lactose takes place in establishments officially approved by the relevant competent authority. The Health marks for these establishments are:
  - FrieslandCampina DMV B.V. (NCB-Laan 80, 5462GE Veghel, The Netherlands): NL Z0032 EG (Manufacturing of pharmaceutical grade lactose)
  - FrieslandCampina Ingredients B.V. (Needseweg 23, 7271AB Borculo, The Netherlands): NL Z0199 EC (Manufacturing of pharmaceutical grade lactose)
  - DFE Pharma B.V. (Needseweg 23, 7271 AB Borculo, The Netherlands): NL Z0984 EC (Processing of pharmaceutical grade lactose)
  - DFE Pharma GmbH & Co. KG (Lauenförder Strasse 5, 37176 Nörten-Hardenberg, Germany): DE NI200 EG (Spray-drying, roller drying or agglomeration of pharmaceutical grade lactose manufactured in the Netherlands)
  - Fonterra Limited (Kaponga, New Zealand): NZ 9370 (Manufacturing of pharmaceutical grade lactose)
  - DFE Pharma (NZ) Limited (Kaponga, New Zealand): NZ 9369 (Processing of pharmaceutical grade lactose)
- Pharmaceutical grade lactose complies with the applicable requirements for importation of milk-derived products in the USA as formulated in 9 CFR Part 94.

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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