Availability of Drug Master Files (DMFs)

Product group: Lactose, Inhalation, MCC, Starch, Biopharma and Superdisintegrants
All products manufactured by DFE Pharma GmbH & Co. KG

Document No.: PD-0121

Dear Customer,

In discussions with the FDA DFE Pharma GmbH & Co. KG was informed that type IV Drug Master Files are not necessary and not helpful for excipients that are described in the USP-NF. Only for drug products applied as dry powder inhalations a Drug Master File for the excipients is necessary and helpful. For excipients used in oral dosage forms reference to a DMF is not necessary because the monograph in the current version of the USP-NF describes the excipients in enough detail.
Nevertheless, DFE Pharma GmbH & Co. KG holds a type IV (excipients) Drug Master File at the FDA in the USA for several of its products (intended for use in oral dosage forms and in drug products applied as dry powder inhalations) listed below.

Product	DMF No.
HMS Lactose DT/SuperTab® 30GR	13102
Inhalation Lactose (Lactohale®)	15909
Inhalation Lactose (produced in New Zealand)	21014
Primojel®	3015
Primellose®	9662
Respitose® SV001	15916
Respitose® SV003/ Respitose® SV010/ Respitose® SV012	16285
Respitose® ML001	14644
Respitose® ML002	16284
Respitose® ML003/ Respitose® ML006	18730
SuperTab® 21AN/ SuperTab® 22 AN/ SuperTab® 24AN/ Respitose® AN001	17577
SuperTab® 11SD (produced in Germany)/ SuperTab® 14SD	17576
Pharmacel®	27249
Co-processed mixture of lactose and lactitol (SuperTab® 40LL)	33935

Such a Drug Master File may be consulted by the FDA in the review process of a submitted NDA by a pharmaceutical company.

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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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