No US DMF requirement

Product group: MCC, Biopharma

Product : Pharmacel® sMCC, BioHale® Sucrose, BioHale® Trehalose Dihydrate

Dear Customer,

Pharmacel® sMCC (Silicified Microcrystalline Cellulose), BioHale® Sucrose and BioHale® Trehalose Dihydrate are products manufactured by DFE Pharma GmbH & Co. KG.

Please note the following:

- Pharmacel® sMCC complies fully with the monograph of "Silicified microcrystalline cellulose" in the current edition of the USP-NF/JPE.
- BioHale® Sucrose complies fully with the monograph of "Sucrose" in the current edition of the Eur. Ph./USP-NF/JP/ChP.
- BioHale® Trehalose Dihydrate complies fully with the monograph of "Trehalose" in the current edition of the Eur. Ph./USP-NF/JP/ChP.

For monographed substances, the FDA has indicated that there is no requirement to submit a Drug Master File (DMF), and that monographed substances will not be reviewed. The practical impact of this is that when submitting drug product dossiers to the FDA, the aforementioned products can be referred to as follows:

- Pharmacel® sMCC as "Silicified Microcrystalline Cellulose"
- BioHale® Sucrose as "Sucrose"
- BioHale® Trehalose Dihydrate as "Trehalose"

and therefore reference to a type IV DMF in the form of a letter of authorization (LoA) is not required.

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 :

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