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January 5, 2023

Re: **Drug Master File (DMF) Statement**

A DMF is not required by the US Food and Drug Administration (FDA). See fda.gov http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm122886.htm which states: "The submission of a DMF is not required by law or FDA regulation. A DMF is submitted solely at the discretion of the holder. A DMF is a submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The information contained in the DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments and supplements to any of these."

Zochem is not claiming any confidential information and its ingredients and process is public information available to customers for their NDA as required.

Please contact your commercial representative, customer service, or the Zochem technical department representative(s) below for any further questions.

Regards,

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