

Zochem LLC (Zochem South)
600 Printwood Drive
Dickson, TN 37055, USA
CustomerService@Zochem.com
PHONE (615) 446-8791
FAX (615) 446-8789



Zochem ULC (Zochem North)
1 Tilbury Court, Brampton
Ontario, L6T 3T4, Canada
Orders@Zochem.com
PHONE (800) 324-1806
FAX (905) 453-2920

March 22, 2018

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

A DMF is not required by the USFDA. See [fda.gov](http://www.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 Drug Master File (DMF) is a submission to the Food and Drug Administration (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.

Regards,

John J. Stourac

John Stourac, C.Q.E.
Director – Technical, Regulatory and ES&H
Zochem
+1 312 813 4620
Email: jstourac@zochem.com