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Dear Valued Customer,

Calumet Refining, LLC USP/NF Mineral Oils, White Petrolatums USP and Petrolatums USP fully comply with the requirements of *General Chapter <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests* in the current edition of the United States Pharmacopoeia/National Formulary (USP/NF).

The USP/NF products Calumet produces are anhydrous hydrocarbons which do not support microbiological growth. Our USP/NF products are derived solely from petroleum feedstocks. The feedstocks are processed through a hydrotreater at 3,000 pounds of pressure at 550°F for a minimum of 30 minutes. There is no possibility of microbiological growth in these products. Therefore, Calumet does not test every batch of product for microbiological growth, nor do we report microbiological testing information on our Certificates of Analysis.

Testing conforming to *USP/NF Chapter <61>* is completed by an outside testing facility on an annual basis on various mineral oils and petrolatums. The results clearly demonstrate that these products pass the current edition of the USP/NF. Due to the similar nature of our USP/NF mineral oils and petrolatums, we expect similar results for all our USP/NF products.

Calumet understands customers may have concerns about microbiological testing not being completed on every batch, and we are happy to work with our customer should a discrepancy arise. If a customer has a failing result *USP/NF Chapter <61>* testing, the following shall apply:

- A two-pound sample of the product in question will be sent to Calumet Refining, LLC for testing.
- Calumet will use an outside testing facility to conduct *USP/NF Chapter <61>* testing on the returned customer sample and the Calumet retain.
- If both samples pass, Calumet will not accept the return of the batch in question.
- If either sample fails, Calumet will accept the return of the failing batch. Calumet will work with the customer to determine the root cause of the failure.

This policy shall apply to direct customers only. Indirect customers must address the issue with their supplier.

If you have any further questions concerning microbiological testing, please do not hesitate to contact our product support department.

Sincerely,

Lynn Massad
Technical Market Development Manager