From: Misock, John
To: <u>Turcovski, Susan M</u>

Cc: Dewan, Kapal; Sadrieh, Nakissa

Subject: Request for inspection of Chemco Corp., Miami Lakes, FL

Date: Friday, August 5, 2016 3:19:54 PM

Susan,

I have a favor to ask of you. Florida District has performed two inspections of Van Tibolli, own brand distributor of GK Hair Taming System. These products contain formaldehyde-releasing chemicals, which FDA has determined to cause the products to be adulterated in the absence of effective warning statements. Thanks in part to the excellent work Florida District has performed, the agency is considering further limiting the use of these chemicals. In order to support this decision we are asking Fla-DO to inspect the contract manufacturer for Van Tibolli, Chemco Corp. 4920 NW 165 St, Miami Lakes, FL 33014, (FEI: 1042599) to gather additional information in.

Due to the expedited need we are asking that Fla-DO perform this inspection as soon as it can be added to your work plan. This inspection has priority over any cosmetic inspections planned for the FY2015 or FY2016 assignments.

OCAC SME's will provide detailed guidance for your investigator(s). I will be on leave from August 9th to the 19th. In the interim, you and your staff may contact Kapal Dewan, OCAC Team Leader to arrange for further guidance and a pre-inspection conference call.

Thanks in advance for your assistance!

Best regards,

John Misock

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