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**PURGED** *AK*

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

June 29, 2000

xc: HFI-35  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 00 - 40

Curtis F. Mueller  
President  
Mueller Sports Medicine, Inc.  
One Quench Drive  
Prairie du Sac, Wisconsin 53578

Dear Mr. Mueller:

This is in reference to "Mueller Foot & Body Powder" and "ISO-HEX ANTISEPTIC—FUNGICIDAL WASH" which are manufactured by your firm. "Mueller Foot & Body Powder" is labeled for relief of athlete's foot and friction reduction, and the active ingredients are talcum powder and zinc undecylenate. "ISO-HEX" is labeled as "a cleaning agent for open wounds" and contains "2,4,4-Trichloro, 2-Hydroxydiphenyl ether and Isopropanol" as the active ingredients. Based on the claims listed above, "Mueller Foot & Body Powder" and "ISO-HEX" are drugs [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)]. Further, because of their labeled claims, they are subject to the Final Monograph for Topical Antifungal Drug Products (Title 21, Code of Federal Regulations, Part 333, Subpart C [21 CFR 333]). The products fail to comply with the final regulations in that the active ingredients are not permitted by the regulation (21 CFR 333.210), and the labeling does not bear the required statement of identity, indications, warnings and directions for use [21 CFR 333.250(a), (b), (c) and (d)].

Based on the above, "Mueller Foot & Body Powder" and "ISO-HEX" are "new drugs" that may not be legally marketed because no application has been approved for these products (Section 505 of the Act). The products are misbranded [Section 502(f)(1) and 502(f)(2) of the Act] because their labeling fails to bear adequate directions for use and required warnings.

The list of violations above is not intended to be construed as all-inclusive of those that exist in your firm. It is your responsibility to ensure that all of your firm's products are in compliance with all requirements of the Act and implementing

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Curtis F. Mueller  
June 29, 2000

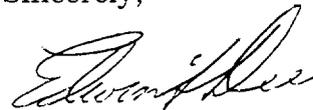
regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This action may include seizure and/or injunction.

We received Dennis J. Breunig's letter dated March 14, 2000 (copy enclosed), which discusses corrective actions taken in response to our inspection of March 6, 8 and 10, 2000. A copy of the form FDA-483 from that inspection is also enclosed. It is your responsibility to ensure that these and any other GMP deviations are corrected.

Please notify this office within 15 days of receipt of this letter of the specific actions taken to correct the noted violations, including an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,



Edwin S. Dee  
Acting Director  
Minneapolis District

TGP/ccl

Enclosure: FDA-483, 3/10/00  
Bruenig to Rahto, 3/14/00  
21 CFR 333