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

August 6, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 41

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

Dear Mr. Mueller:

During our inspection of your over-the-counter (OTC) drug and device manufacturing facility located in Prairie du Sac, WI, our investigator found serious violations of the current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your OTC drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

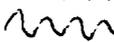
The violations observed during our inspection include but are not limited to the following:

1. Failure to follow your written stability testing program (21 CFR 211.166) in that there is no active ongoing stability testing program.
2. Failure to calibrate instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program

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containing specific directions, schedules, etc. [21 CFR 211.160(b)(4)] in that the scale and IR Spectrophotometer are not calibrated  as stated in your standard operating procedure (SOP).

3. Failure to establish control procedures to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product [21 CFR 211.11(a)] in that there is no documentation that any formal process validation has been conducted on drug products.
4. Failure to test each component for conformity with all appropriate written specifications for purity, strength and quality [21 CFR 211.84(d)(2)] in that no certificates of analysis have been received in lieu of potency/purity testing.
5. Failure to assure uniformity from batch to batch by preparing master production and control records for each drug product, including batch size. These master production and control records shall be prepared, dated and signed (full signature, handwritten) by one person and independently checked, dated and signed by a second person [21 CFR 211.186(a)]. Your master formula records have not been reviewed, signed and dated by one individual and rechecked, signed and dated by a second individual.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so 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. Possible actions include seizure and/or injunction. This is official notification that FDA expects all your locations to be in compliance.

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Please be aware that all device manufacturers are required to have written medical device reporting (MDR) procedures. However, there are exceptions to every rule. Those excluded from MDR reporting requirements include dentists, doctors, optometrists, nurse practitioners, school clinics, employee health clinics, and free-standing care units. Manufacturers or user facilities may request exemptions or variances from any or all of the reporting requirements in 21 CFR 803.

You should notify this office in writing within 15 working days of receipt of this letter of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

We note that we previously issued you a Warning Letter regarding the same drug GMP problems on August 12, 1994. We believe it is prudent to have you meet with us in our Minneapolis office. We have scheduled a meeting for Thursday, September 2, 1999, at 1:00 p.m. Please bring copies of documentation demonstrating that corrections have been made. If the meeting arrangements conflict with your schedule, please contact Ms. Hoffman at (612) 334-4100 ext. 159 to make other arrangements.

Sincerely,



James A. Rahto
Director
Minneapolis District

CAH/ccl