

WISCONSIN DEPARTMENT OF REGULATION & LICENSING



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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

In The Matter Of The Application For
A License To Manufacture Pharmaceuticals Of:

MUELLER SPORTS MEDICINE, INC.	FINAL DECISION AND ORDER
	GRANTING LICENSE
Applicant	LS0203121PHM

01 PHM 064

The parties to this action for the purposes of §227.53, Wis. Stats., are:

Mueller Sports Medicine, Inc.
One Quench Drive, HWY PF
Prairie du Sac, WI 53578

Wisconsin Pharmacy Examining Board
P.O. Box 8935
Madison, WI 53708-8935

Department of Regulation and Licensing
Division of Enforcement
P.O. Box 8935
Madison, WI 53708-8935

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final decision of this matter, subject to the approval of the Board. The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following:

FINDINGS OF FACT

1. The applicant, Mueller Sports Medicine, Inc., is a Wisconsin corporation engaged in the manufacture of drugs as that term is defined by 21 USC sec. 321(g)(1) and Wis. Stats. sec. 450.01(10).
2. The principal address of the applicant is One Quench Drive, Prairie du Sac, WI 53578.
3. The applicant commenced business in 1963 and has never obtained a Wisconsin manufacturer’s license as required by Wis. Stats. sec. 450.07(1). The applicant first received actual knowledge that it is required to obtain a Wisconsin manufacturer’s license in October, 2001, and has promptly filed a application with the Department.
4. On May 23, 2001, a consent decree and order was issued by the United States District Court for the Western District of Wisconsin in case 01-C-0049-C, which among other things, determined that the applicant’s "methods used in, and the facilities or controls used for, [the] manufacture, processing, packing and holding [of certain drug products] do not conform to, or are not operated or administered in conformity with [current good manufacturing practices]".

5. As a result of the consent decree and order the applicant is subject to inspection by, and reporting to, the United States Food and Drug Administration to assure continued conformity with "current good manufacturing practices" regulations.

CONCLUSIONS OF LAW

6. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to §450.07, Wis. Stats. and is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED, that the attached Stipulation is accepted.

IT IS FURTHER ORDERED, that, a LIMITED license to manufacture pharmaceuticals shall be granted to Mueller Sports Medicine, Inc., upon filing of a complete and current application and payment of the statutory fees, subject to the following terms and conditions:

1. Mueller Sports Medicine, Inc. shall at all times comply with "current good manufacturing practices" and with all other state and federal laws and regulations pertaining to its business as a drug manufacturer.

2. Mueller Sports Medicine, Inc., shall comply with all requirements of the consent decree and order entered in United States District Court case 01-C-0049-C. Mueller Sports Medicine, Inc. may be subject to discipline by the Board under the said consent decree and order only if the United States District Court finds, or it is otherwise decreed, that Mueller Sports Medicine, Inc. violated the consent decree and order.

3. Mueller Sports Medicine, Inc. shall notify the Board, through the Department Monitor, of any inspection performed by an FDA inspector or FDA compliance officer that relates to drug manufacturing, and shall promptly transmit copies of any correspondence or reports between Mueller Sports Medicine, Inc. and the FDA (or any agency acting on behalf of the FDA) concerning such inspections to the Department Monitor, at the Department of Regulation and Licensing, Division of Enforcement, P.O. Box 8935, Madison, WI 53708-8935; FAX (608) 266-2264; Tel. (608) 267 3817.

4. The requirements set forth in paragraphs 2 and 3 of this Order, above, shall cease at the time Mueller Sports Medicine, Inc. is granted relief from the consent decree and order from the United States District Court in case 01-C-0049-C pursuant to paragraph 19 of the consent decree and order.

5. Mueller Sports Medicine, Inc. shall cooperate with any reasonable request by employees of the Department of Regulation and Licensing for information or access relating to its manufacturing activity.

6. Mueller Sports Medicine, Inc. shall pay COSTS in this matter in the amount of \$400.00, to the Department of Regulation and Licensing within 30 days of this order.

7. Mueller Sports Medicine, Inc. shall pay a FORFEITURE in the sum of \$ 1,000.00, to the Department of Regulation and Licensing, within 60 days of the date of this Order.

IT IS FURTHER ORDERED, that pursuant to §227.51(3), Wis. Stats., and ch. RL 6, Wis. Adm. Code, if the Board determines that there is probable cause to believe that Applicant has violated any term of this Final Decision and Order, the Board may order that the license of respondent be summarily suspended pending investigation of the alleged violation.

Dated this 12th day of March, 2002.

WISCONSIN PHARMACY EXAMINING BOARD

Susan Sutter

A Member of the board