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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY

PROCEEDINGS AGAINST:

RADIX LABORATORIES, INC.,	**FINAL DECISION AND ORDER**
RESPONDENT	LS0012122PHM

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

Radix Laboratories, Inc.

1334 International Dr.

Eau Claire, WI 54701

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. Respondent Radix Laboratories, Inc., a Wisconsin corporation, is and was at all times relevant to the facts set forth herein a drug manufacturer licensed in the State of Wisconsin pursuant to license #269, originally granted on 3/15/95. Respondent is also a licensed drug distributor pursuant to license # 722, originally granted on 3/15/95. Respondent holds limited licenses by virtue of an Order issued by the Board on March 15, 1995, as modified by the Board's Order dated June 21, 1996.

2. On or about March 1, 1999, the United States Food & Drug Administration (FDA) filed an action in the federal District Court for the Western District of Wisconsin, alleging that respondent has failed to comply with Current Good Manufacturing Practice in its manufacturing processes, and requesting an injunction. Following the filing of the March 1, 1999, action in federal court, respondent agreed that it would, in lieu of possible summary suspension, notify the Board's prosecuting attorney 7 days before resuming operations.

3. Failure to comply with CGMP, if proved, would violate that provision of the March 15, 1995 Board Order, which states:

> Radix Laboratories shall at all times comply with Good Manufacturing Practices and with all other state and federal laws and rules related to manufacturing and distributing.

4. The FDA action is based in part upon an inspection report by FDA inspectors who inspected respondent's facility on June 2-30, 1998, and alleged numerous violations of Current Good Manufacturing Practice, detailed in a 25 page, 98 item, FDA form 483, which was furnished to respondent on or about June 30, 1998. On July 6 and August 20, 1998, respondent provided written responses to the FDA. On November 25, 1998, the FDA wrote to respondent stating that respondent's formal response to the FDA form 483 was inadequate in multiple respects. Respondent then provided an additional written response to the FDA on or about November 25, 1998.

5. The Order of March 15, 1995 contains the following provision, which has not been modified by the Board:

> Radix Laboratories shall report to the Department Monitor whenever it is visited by a Food & Drug Administration inspector, compliance officer, or similar employee, and shall immediately transmit all correspondence and reports received from or sent to the FDA (or other federal agency on behalf of the FDA), to the Department Monitor.

6. Respondent did not notify the Board of the inspection, the issuance of the FDA 483 form, respondent's responses, or the FDA's correspondence regarding the inadequacy of the Radix response to the FDA 483, until January 6, 1999.

7. Respondent's manufacturing practices as set forth in the June, 1999, FDA form 483 allege multiple violations of Current Good Manufacturing Practice.

8. The FDA did a followup inspection of respondent on and between December 14, 1998, and January 14, 1999. At that time, multiple uncorrected problems were alleged in a new form 483, all of which would be, if proved, violations of Current Good Manufacturing Practice.

9. The January 14, 1999, FDA 483 was not timely filed with the Department Monitor.

10. Respondent has conducted 17 voluntary recalls of its products in the past five years because they have been found to contain a precipitate which could have harmed an animal if the product had been injected. Respondent has also received nine reports from customers that animals have died or become ill following administration of respondent's injectable products. Respondent's quality control investigations of these incidents found that no precipitate was in any of the questioned products at the time of use, and found insufficient evidence that the problems reported were caused by a faulty product as opposed to inappropriate use or some other cause.

11. Respondent stipulated to a consent decree with the FDA in April, 1999, settling the federal charges by agreeing to future compliance without admitting any wrongdoing, and agreeing to await FDA inspection and permission before resuming operations. Respondent did not provide the Department Monitor with a copy of this document until June 14, 1999.

12. Respondent received a letter dated November 2, 1999, from the FDA giving him permission to resume operations, but did not file that letter with the Department Monitor until February 21, 2000.

13. Respondent resumed manufacturing operations without notice to the Board's prosecutor, in November, 1999, pursuant to the consent decree and the November 2, 1999 letter from the FDA. Notice was given on February 21, 2000, that distribution of product would begin in March, 2000.

14. The owner and president of respondent, Mr. Premchand Girdhari, has been debarred by the FDA from providing any service in any capacity to any firm or person holding an approved or pending New Drug Application, pursuant to §306(a) of the federal Food, Drug & Cosmetic Act. The order was effective January 21, 2000. Radix Laboratories, Inc. assures the Board that it does not hold an NDA or produce any drugs requiring an NDA.

CONCLUSIONS OF LAW

A. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to §450.10, Wis. Stats. and is authorized to enter into the attached Stipulation pursuant to §227.44(5), Wis. Stats.

B. The conduct described in paragraphs 6, 9, and 11-12, above, violated §450.10(1)(a) 8., Wis. Stats. and § Phar 10.03(18) Wis. Adm. Code. Such conduct constitutes unprofessional conduct within the meaning of the Code and statutes.

ORDER

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

IT IS FURTHER ORDERED, that respondent shall FORFEIT $500, to be paid before any of respondent's licenses is renewed.

IT IS FURTHER ORDERED, that all provisions of the past Orders of the Board shall remain in effect unless specifically modified. Respondent shall, within 1 business day of receipt, forward copies of any and all

correspondence, faxes, e-mails, and other documents received from the FDA (or any agency on its behalf) by any means whatever, to the Department Monitor. Respondent shall not manufacture any drug requiring an NDA without approval of the Board.

IT IS FURTHER ORDERED, that respondent shall pay COSTS in this matter in the amount of $750, within 60 days 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 respondent 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 December 8, 2000.

WISCONSIN PHARMACY EXAMINING BOARD, by:

John P. Bohlman

A member of the board