

## WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES



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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

RADIX LABORATORIES, INC.,  
Applicant.

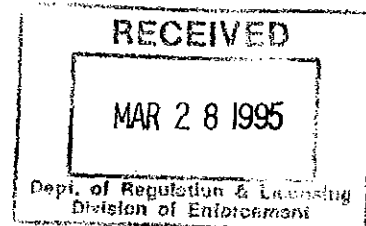
FINAL DECISION AND ORDER  
GRANTING LIMITED LICENSES  
94 PHM 106

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

Radix Laboratories, Inc.  
1334 International Drive  
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. Applicant Radix Laboratories, Inc. is and was at all times relevant to the facts set forth herein a Wisconsin corporation engaged in the manufacture and distribution of veterinary drugs, as that term is defined in ch. 450, Wis. Stats.
2. Applicant commenced business in 1979 and has never obtained a license from the board to manufacture or to distribute drugs. Applicant first had actual knowledge that it was required to obtain such licenses in 1994, and promptly applied for licensure as a manufacturer. It will immediately apply for a license as a distributor, based on this stipulation and Final Order.
3. On September 13, 1994, the board denied the application for licensure because applicant's president and sole shareholder, Premchand Girdhari, had been convicted in 1991 of violating the Food, Drug & Cosmetic Act in that in 1986 the firm failed to comply with Good Manufacturing Practices in manufacturing its products (thus rendering them "adulterated" within the meaning of the Act), and of making false statements to FDA officials. The board also noted that in 1992 the Veterinary Examining Board revoked Girdhardi's Animal Technician license as a result of his conviction. Girdhari continues to be on probation to federal authorities for that conviction, and is scheduled to be discharged from probation in June, 1995.

4. At all times since 1986, Radix Laboratories, Inc., has continued to be an FDA approved manufacturer, and has undergone regular inspection by FDA. Those inspections have not resulted in any enforcement or penal action against Radix Laboratories.

5. In January, 1995, applicant retained an outside consultant who audited the manufacturing practices then in use. The consultant's report has been reviewed by the board. The report concludes that applicant is in substantial compliance with Good Manufacturing Practice requirements.

### CONCLUSIONS OF LAW

3. 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, and a separate LIMITED license to distribute, shall be granted to Radix Laboratories, Inc., upon filing of complete and current applications and payment of the statutory fees, and subject to the following conditions:

Radix Laboratories shall not manufacture any product intended or labeled for human use other than aqueous solution of the volatile salts or distillate of *Sarracenia purpurea*, without approval of the Board. Radix Laboratories shall not distribute any drug which it has not itself manufactured, without approval of the Board.

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.

Radix Laboratories shall, at its own expense, retain a qualified expert consultant acceptable to the Board, to audit Radix Laboratories' manufacturing (including recordkeeping) operations in their entirety, on a quarterly basis. The full report of such audit shall certify that, in the consultant's professional judgment, the firm is using Good Manufacturing Practices, and the full report shall be furnished to the department's compliance monitor no later than April 15, and quarterly thereafter, for so long as this limitation is in effect.

At such time as no shareholder or officer of Radix Laboratories is on probation and is not charged with or awaiting sentence for any offense related to pharmaceutical manufacturing, and is not under any sanction or the subject of any civil proceeding by the US Food and Drug Administration or any other federal or state regulatory authority, Radix Laboratories may petition the Board to modify or terminate these limitations and grant a less limiting or an unlimited license to Radix Laboratories as a manufacturer. The granting of such a petition shall be solely within the discretion of 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.

IT IS FURTHER ORDERED, that Radix Laboratories shall, at all times while it is licensed by the Board, require all of its employees to cooperate fully with the US Food & Drug Administration and the Wisconsin Department of Regulation & Licensing, including by answering in an unsupervised setting all legitimate questions of the FDA and the Department truthfully and completely and by providing full access to its premises, records, and employees during hours of actual operation. Notice of this requirement shall be provided to all employees in a form approved by the Board.

IT IS FURTHER ORDERED, that Radix Laboratories is REPRIMANDED for its failure to apply for licenses between 1979 and 1994.

IT IS FURTHER ORDERED, that respondent shall pay the COSTS of this proceeding in the amount of \$500, within 30 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 applicant has violated any term of this Final Decision and Order, the Board may order that either or both licenses of applicant be summarily suspended pending investigation of the alleged violation.

Dated this 15<sup>th</sup> day of March, 1995.

WISCONSIN PHARMACY EXAMINING BOARD

by: Thomas M. DeGor  
a member of the board

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STATE OF WISCONSIN  
BEFORE THE PHARMACY EXAMINING BOARD

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In the matter of the application	:	
for a license to manufacture	:	
pharmaceuticals of	:	STIPULATION
RADIX LABORATORIES, INC.,	:	
Applicant.	:	94 PHM 106

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It is hereby stipulated between the above applicant and the undersigned prosecuting attorney for the Division of Enforcement of the Department of Regulation and Licensing, as follows:

1. This Stipulation is entered into as a result of a request for hearing on the Board's denial of the application of Radix Laboratories, Inc., for a manufacturing license, and its concomitant need for a distributor license.

2. Applicant understands that by signing this Stipulation, applicant waives the following rights with respect to further proceedings: a right to a hearing; the right to call witnesses on applicant's behalf and to compel attendance of witnesses by subpoena; the right to testify personally; the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision; the right to petition for rehearing; and all other applicable rights afforded to applicant under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, and the Wisconsin Administrative Code.

3. Applicant is aware of applicant's right to seek legal representation and has obtained legal advice before signing this Stipulation.

4. Applicant agrees to the adoption of the attached Final Decision and Order by the Board. The parties consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Applicant waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation or the proposed Final Decision and Order, and the matter shall be returned to the Division of Enforcement for further proceedings. In the event that this Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

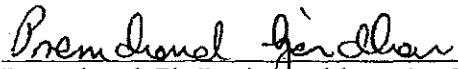
6. The parties agree that an attorney for the Division of Enforcement may appear before the Board, in open or closed session, without the presence of applicant or applicant's attorney, for the purposes of speaking in support of this agreement and answering questions that the members of the Board and its staff may have in connection with their deliberations on the case.

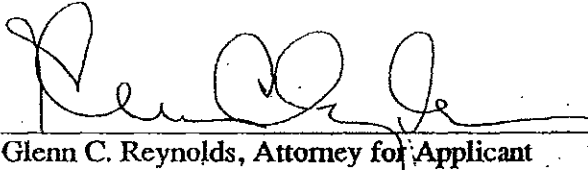
7. The Board Advisor in this matter may participate freely in any deliberations of the Board regarding acceptance of this Stipulation and the proposed Final Order, and may relate to the Board any knowledge and views of the case acquired during the investigation.

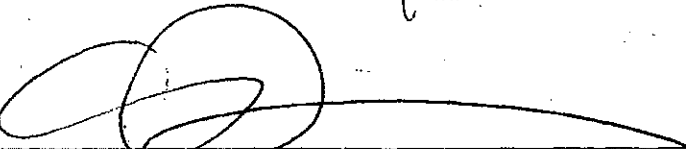
8. The Division of Enforcement joins applicant in recommending that the Board adopt this Stipulation and issue the attached Final Decision and Order.

9. Applicant is informed that should the Board adopt this stipulation, the board's final decision and order is a public record and will be published in the Monthly Disciplinary Report issued by the department. A summary of the order will be published in the Wisconsin Regulatory Digest issued semiannually by the Board. This is standard department procedure and in no way specially directed at applicant.

RADIX LABORATORIES, INC., by:

  
Premchand Girdhari, President, Applicant 3-23-95  
Date

  
Glenn C. Reynolds, Attorney for Applicant 3-24/95  
Date

  
Arthur Thexton, Prosecuting Attorney  
Division of Enforcement 3/27/95  
Date

