WISCONSIN DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES

Wisconsin Department of Safety and Professional Services
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STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF THE LIMITED LICENSES OF RADIX LABORATORIES, INC., LICENSEE.	: : : : :	MODIFICATION OF LIMITED LICENSES (June, 1996)

To: Radix Laboratories, Inc.
1334 International Drive
Eau Claire, WI 54701

On March 15, 1995, the State of Wisconsin Pharmacy Examining Board issued a Final Decision and Order Granting Limited Licenses in which the applicant, Radix Laboratories, Inc. was granted licenses as a manufacture and as a distributor. Both licensees were granted subject to various limitations, including the filing of quarterly reports regarding the results of quarterly audits of the licensee's manufacturing practices respecting specifically its utilization of Good Manufacturing Practices ("GMP"). The board's order required that the limitations remain intact at least until such time as no shareholder or officer of Radix Laboratories is on probation or charged with or awaiting sentence for any offense related to pharmaceutical manufacturing.

By letter dated June 14, 1995, the attorney for Radix Laboratories informed the board that the licensee's president and sole shareholder, Premchand Girdhari, had successfully completed the probation resulting from a prior conviction for violation of the Food, Drug & Cosmetic Act. The correspondence enclosed a copy of the probation officer's "Probation/Supervised Release Termination" letter dated June 7, 1995. The licensee requested that the auditing and reporting requirements be reduced to a semi-annual basis.

The board denied that request, as only one report had been submitted at that time under the order. The board indicated that the licensee should comply with the order for a period of at least one year prior to applying for a modification of the requirement.

By letter dated May 28, 1996, the attorney for Radix Laboratories again requested that the quarterly GMP audit and reporting requirements within the board's order be reduced.

On June 12, 1996, the board reviewed and discussed the request, materials submitted and the file in this matter. Based upon the materials submitted, the board granted the licensee's request, as follows:

ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED that the Final Decision and Order Granting Limited Licenses, dated March 15, 1995, as a manufacturer and as a distributor to Radix Laboratories, Inc., is modified in the related provision thereof to provide as follows:

> Radix Laboratories shall, at its own expense, retain a qualified expert consultant acceptable to the Board, to audit Radix Laboratories' manufacturing (including record keeping) operations in their entirety. The full report of such audit shall certify that, in the consultant's professional judgment, the firm is using Good Manufacturing Practices. A full report shall be completed and furnished to the department's compliance monitor no later than December 15, 1996. If the report is determined to be satisfactory by the board, Radix Laboratories shall only be required to have completed and furnished full reports on each and every June 15th and December 15th thereafter, for so long as this limitation is in effect. If the report due December 15, 1996 is found not to be satisfactory by the board, the auditing and reporting requirement shall revert to a quarterly basis, the first such subsequent report being due on March 15, 1997.

FURTHERMORE, IT IS HEREBY ORDERED that in all other respects the Final Decision and Order Granting Limited Licenses, dated March 15, 1995, remains in full force and effect.

Dated this 21st day of June, 1996.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

George F. Christiansen

George F. Christiansen, R.Ph.
Chairman

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