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STATE OF WISCONSIN

BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY

PROCEEDINGS AGAINST

CELLETECH, LTD.,	**FINAL DECISION AND ORDER**
RESPONDENT.	99 PHM 44
	LS 9907221 PHM

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

Celletech, Ltd.
518 Tasman Ct.
Madison, WI 53714

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 is Celletech, Ltd., a Wisconsin corporation. Celletech, Ltd., was licensed as a drug manufacturer in the State of Wisconsin pursuant to license #297, which license was granted on July 13, 1999. Respondent did not renew its license, which expired on May 31, 2000.
2. Beginning in 1987 and continuing to the present, respondent was engaged in the business of manufacturing products represented and labeled as homeopathic preparations, intended for human consumption. Respondent has, on a weekly basis, in fact sold such products in both intrastate and interstate commerce.
3. The products manufactured by respondent are intended and labeled as intended for use in the cure, mitigation, treatment or prevention of disease or other conditions in persons. Additionally and alternatively, they are labeled as intended to affect one or more functions of the human body.
4. Some of these products are listed as homeopathic preparations in the official Homeopathic Pharmacopoeia of the United States. Respondent also manufactured products not so listed, and offered them for sale, labeled as homeopathic drug products.
5. At all times material to the matters set forth herein, substantially all of the products labeled as homeopathic drug products or preparations which were manufactured by respondent were produced by the use of a device called the "Rae Potency Simulator" manufactured by Magneto Geometric Application, of England. This manufacturing method is not listed in the Homeopathic Pharmacopoeia of the United States.
6. The Potency Simulator is said to use magnetic forces to create a precise pattern which is imprinted into

molecules which are then transferred to tablets or similar solid dosage forms, to be ingested by human beings for the purpose of treating disease or improving health. Respondent has not produced any scientific evidence that the device does, in fact, produce a homeopathic product equivalent to those produced by methods set forth in the Homeopathic Pharmacopoeia of the United States, and respondent has not shown scientifically that it does so.

7. Respondent engaged in its activities of manufacturing preparations labeled as drugs and drug products as described above without a license granted by the Board during all or parts of the calendar years 1987 through 1999 inclusive.
8. Respondent has agreed to discontinue all labeling of any product as a "drug" within the meaning of §450.01(10), Wis. Stats., and to surrender its right to renew its manufacturing license.

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. The Board has adopted the standards of the Food, Drug & Cosmetic Act, and the Good Manufacturing Practice regulations adopted under the Act, as the Board's own standards.
B. All the preparations referred to in ¶¶ 2-4, above, are "drugs" within the meaning of §450.01(10), Wis. Stats. because of their labeling.
C. The use of the Potency Simulator violates § Phar 12.03(2)(d), Wis. Adm. Code, in that its use does not comply with Current Good Manufacturing Practice, in particular 21 CFR §211.160(4). The products so manufactured and sold are adulterated within the meaning of §501(a)(1)(b), Food, Drug & Cosmetic Act (21 USC §351). Such conduct subjects respondent to disciplinary action by the Board, pursuant to § Phar 12.05, Wis. Adm. Code.
D. Respondent has produced no scientific evidence that the Potency Simulator does, in fact, produce a homeopathic drug product, and the sale of products made by use of the device, labeled and represented as homeopathic products, violates §450.10(1)(a)4., 5., and 7., Wis. Stats., and § Phar 10.03(11), Wis. Adm. Code, and such violation subjects respondent to discipline.
E. The labeling and sale of products made by use of the Potency Simulator, as homeopathic drug products, renders the products mislabeled under §301(a), Food, Drug & Cosmetic Act (21 USC §331). Sale of such products subjects respondent to discipline under §450.10(1)(a)2., Wis. Stats. Alternatively and additionally, to label such products as being homeopathic drugs renders them misbranded in violation of §502(a), Food, Drug & Cosmetic Act (21 USC §352). Such conduct subjects respondent to disciplinary action by the Board, pursuant to § Phar 12.05, Wis. Adm. Code.
F. The manufacture and sale of any product represented to be a homeopathic drug product, which is not listed in the official Homeopathic Pharmacopeia of the United States (or is otherwise not generally recognized as a homeopathic preparation), or which is produced by methods other than those listed in the United States Homeopathic Pharmacopeia, is the manufacture and sale of an unapproved new drug and is contrary to 21 USC §355 (§505, Food Drug & Cosmetic Act). Such conduct subjects respondent to discipline under §450.10(1)(a)2., Wis. Stats.
G. The conduct described in ¶7, above, violates 450.07(1), Wis. Stats., and subjects respondent to discipline under §450.10(1)(a)2., Wis. Stats.

ORDER

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

IT IS FURTHER ORDERED, that the SURRENDER of the right to renew the manufacturer's license of Celletech, Ltd., is ACCEPTED, effective the date of this order.

IT IS FURTHER ORDERED, that respondent shall not manufacture any drug, or any item labeled as a drug or drug product, without a valid license.

IT IS FURTHER ORDERED, that respondent shall pay the COSTS in the amount of $11,163.29, by December 31, 2000.

Dated this June 14, 2000.

WISCONSIN PHARMACY EXAMINING BOARD,

by:

John Bohlman, R.Ph.

a member of the board

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