

# WISCONSIN DEPARTMENT OF REGULATION & LICENSING



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STATE OF WISCONSIN  
BEFORE THE CHIROPRACTIC EXAMINING BOARD

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IN THE MATTER OF THE DISCIPLINARY :  
PROCEEDINGS AGAINST :  
: FINAL DECISION AND ORDER  
JENNIFER LINN RADA, D.C., : LS0706281CHI  
RESPONDENT. :

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[Division of Enforcement Case # 06 CHI 043]

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

Jennifer Linn Rada, D.C.  
3611 Shepherd Lane  
Manitowoc, WI 54220

Division of Enforcement  
Department of Regulation and Licensing  
1400 East Washington Avenue  
P.O. Box 8935  
Madison, WI 53708-8935

Wisconsin Chiropractic Examining Board  
Department of Regulation and Licensing  
1400 East Washington Avenue  
P.O. Box 8935  
Madison, WI 53708-8935

PROCEDURAL HISTORY

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 Chiropractic Examining 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. Jennifer Lin Rada, D.C., Respondent, date of birth February 14, 1971, is licensed by the Wisconsin Chiropractic Examining Board to practice chiropractic in the state of Wisconsin pursuant to license number 3703, which was first granted October 4, 2000.

2. Respondent's address of record with the Department of Regulation and Licensing is 3611 Shepherd Lane Manitowoc, WI 54220.

3. At all times relevant to this matter, Respondent was the sole proprietor of Apple Chiropractic Clinic, 814 Jay Street, Manitowoc, Wisconsin, where she was engaged in the practice of chiropractic. At all times relevant to this matter Respondent was the individual solely responsible for approving content of the advertisements for Apple Clinic.

4. On or about July 1, 2006, Respondent approved an advertisement which she subsequently caused to be published in the Manitowoc Herald Times Reporter. The advertisement indicated that Apple Clinic offered cold lasers "to reduce pain and speed up the healing process."

5. Additionally, the advertisement said that “the laser penetrates deep into the tissue and stimulated cells to heal and repair at a much accelerated rate.”

6. Finally, the advertisement asserted that the cold lasers used by Apple Chiropractic Clinic were “Erchonia Lasers which are the only TRUE low-level lasers to be FDA approved.”

7. Erchonia lasers have not received premarket *approval* by the FDA. Rather, Erchonia lasers have received “market clearance” from the FDA as “lamp[s], non-heating, for adjunctive use in pain therapy.”

8. Premarket clearance does not constitute premarket approval by the FDA; premarket clearance lacks assurances of safety and efficacy inherent in the premarket approval process. Premarket clearance means only that a device is substantially equivalent to a legally marketed device NOT subject to premarket approval.

9. On January 17, 2003, when the FDA notified Erchonia’s manufacturer of its market clearance, the FDA specified that “issuance of [market clearance] does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.”

10. The FDA’s notification concerning Erchonia’s market clearance specifically referred its recipient to 21 CFR Part 807.97, entitled, “Misbranding by reference to premarket notification” which reads, in pertinent part:

[Market clearance] does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the [market clearance procedure] is misleading and constitutes misbranding.

11. The FDA’s notification concerning Erchonia’s market clearance cleared the device only for purposes of “adjunctive use in providing temporary relief of minor chronic neck and shoulder pain of musculoskeletal origin.” The FDA did not clear the device for marketing for use in permanent healing, nor for temporary relief of pain which is other than “minor.”

12. Respondent admits that Erchonia is not the only device of its kind to receive market clearance from the FDA.

### CONCLUSIONS OF LAW

1. The Wisconsin Chiropractic Examining Board has jurisdiction over this matter pursuant to Wis. Stat. § 446.03 and authority to enter into this stipulated resolution of this matter pursuant to Wis. Stat. § 227.44(5).

2. Respondent, by engaging in the conduct set out above, has advertised in a manner which is false, deceptive or misleading, which is unprofessional conduct as defined by Wis. Adm. Code § CHI 6.02(15)(a). Respondent is therefore subject to discipline pursuant to Wis. Stat. § 446.03(5).

### ORDER

NOW, THEREFORE, IT IS HEREBY ORDERED:

1. Respondent, Jennifer Linn Rada, D.C., is hereby **REPREMANDED** for the conduct set out above.

2. Respondent shall, within 30 days of the date of this Order, and for a period of 7 consecutive days, publish in the Manitowoc Herald Times Reporter, a notice which has been preapproved by the Board’s designee, and which states as follows:

In the past six months, Apple Clinic has indicated that the cold laser in use at our office was approved by the FDA. This statement is inaccurate. While the FDA has cleared the cold laser device for marketing, the FDA has never tested the device’s safety or efficacy. The cold laser in use by the Apple Clinic has not been approved by

the FDA.

3. Respondent shall provide all patients with whom the Erchronia or other cold laser device is used, a written disclosure which shall be preapproved by the Board's designee, and which includes the following statement:

The [device name] is a cold laser device which has been cleared for marketing by the FDA for temporary relief of minor pain. The [device name] has not been approved by the FDA. The FDA has never tested the efficacy or safety of the [device name].

4. Respondent shall, within 90 days of the date of this Order, pay to the Department of Regulation and Licensing the costs of this proceeding in the amount of \$643.32 pursuant to Wis. Stat. § 440.22(2).

5. Payment shall be mailed or delivered to:

Department Monitor  
Department of Regulation and Licensing  
Division of Enforcement  
1400 East Washington Ave.  
P.O. Box 8935  
Madison, WI 53708-8935  
Fax (608) 266-2264  
Telephone (608) 267-3817

6. This Order is effective on the date of its signing.

Wisconsin Chiropractic Examining Board

By: Steven Silverman D.C.  
A Member of the Board

6/28/07  
Date

STATE OF WISCONSIN  
BEFORE THE CHIROPRACTIC EXAMINING BOARD

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IN THE MATTER OF THE DISCIPLINARY	:	
PROCEEDINGS AGAINST	:	
	:	STIPULATION
JENNIFER LINN RADA, D.C.,	:	LS0706281CHI
RESPONDENT.	:	

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[Division of Enforcement Case # 06 CHI 043]

It is hereby stipulated and agreed, by and between Jennifer Linn Rada, D.C., Respondent; and Sandra L. Nowack attorney for the Complainant, Department of Regulation and Licensing, Division of Enforcement, as follows:

1. This Stipulation is entered into as a result of a pending investigation of Respondent's licensure by the Division of Enforcement (case 06 CHI 043). Respondent consents to the resolution of this investigation by stipulation and without the issuance of a formal complaint.

2. Respondent understands that by signing this Stipulation, she voluntarily and knowingly waives her rights, including the right to a hearing on the allegations against her, at which time the state has the burden of proving those allegations by a preponderance of the evidence; the right to confront and cross-examine the witnesses against her; the right to call witnesses on her behalf and to compel their attendance by subpoena; the right to testify herself; 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 her under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and any other provisions of state or federal law.

3. Respondent has been provided an opportunity to obtain advice of legal counsel prior to signing this Stipulation.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Board. The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent 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, 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 to this Stipulation agree that the attorney or other agent for the Division of Enforcement and any member of the Board ever assigned as a case advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or her attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with the Board's deliberations on the Stipulation. Additionally, any such case advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent 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 accordance with standard Department procedure.

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

Jennifer Linn Rada, D.C.  
Respondent  
3611 Shephert Lane

4/16/07

Manitowoc, WI 54220

Sandra L. Nowack  
Attorney for Complainant  
Division of Enforcement  
Department of Regulation and Licensing  
PO Box 8935  
Madison WI 53708-8935

4/13/07