



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 28 2000

1311 '00 AUG -3 10 04

James M. Cox, II, D.C.
Cox Chiropractic Associates, Inc.
3125 Hobson Road
Fort Wayne, Indiana 46805

Re: Docket No. 00V-1312
Myofasciatron Muscle Stimulator

Dear Dr. Cox:

This responds to your citizen petition, dated May 4, 2000, requesting a variance from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) as it applies to a Myofasciatron muscle stimulator used in your practice. The device has a non-compliant 1/4" phono plug that connects the lead wire to the muscle stimulator. No particular time frame was specified in your citizen petition. You noted that you have contacted the manufacturer, and he does not have any compliant lead wires or adapters to bring this device into compliance.

I am granting a temporary variance until January 1, 2001, to allow time for you to identify an alternative lead wire and adapter supplier. We are aware of numerous muscle stimulator and lead wire manufacturers who produce an adapter for a 1/4" phono plug, and compliant replacement lead wires. One of them should be able to help you. If not, you may contact us again regarding further extension of this variance. If you need further assistance in identifying potential suppliers of lead wire adapters, you may contact Mr. Stewart Crumpler in our Office of Compliance at 301-594-4659.

Note that our investigation also reveals that the manufacturer of your Myofasciatron marketed the device without obtaining the required pre-market clearance from the Food and Drug Administration or complying with other FDA regulations. Therefore, you may not be aware of the enclosed labeling information which is supposed to be included with all muscle stimulators. The manufacturer is no longer in business.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

Enclosure: As stated

00V-1312

VRA1

Specific Labeling Guidance for Powered Muscle Stimulators

PRESCRIPTION STATEMENT

Powered Muscle Stimulators regulated under 21 CFR 890.5850 are regarded as prescription devices. Prescription devices must be labeled prominently with the following prescription statement (both on the device label itself and in the labeling, including the user manual and any advertising and promotional materials), in accordance with 21 CFR 801.109:

"Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device."

USER MANUAL

A user manual should be provided. In addition to the prescription statement described above, a complete manual should include, but not be limited to, the following information:

1. A description of the device and all accessories;
2. Illustrations of the device and accessories;
3. A description of all features, functions, output modalities, and specifications;
4. A description of all user-accessible controls;
5. Indicators, markings, and/or labels on the device which provide information regarding the function or meaning of each control, display, output jack, etc.;
6. A description of the size and type of electrodes to be used with the device;
7. Directions for use;
8. Cleaning and/or maintenance instructions, if appropriate; and
9. Appropriate statements of indications, contraindications, warnings, precautions, and adverse reactions, as described in detail below.

The remainder of this labeling guidance lists statements that should be included prominently in the labeling for powered muscle stimulators. These statements address the indications, contraindications, warnings, precautions, and adverse effects associated with the use of powered muscle stimulators:

INDICATIONS FOR USE

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Muscle re-education
5. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
6. Maintaining or increasing range of motion

Powered muscle stimulators should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

CONTRAINDICATION

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.