



DEC 13 AM 35

Department of
Physical Therapy
December 4, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

The undersigned submits this petition under 21 CFR 898 of the Food and Drug Administration to request the Commissioner of Food and Drugs to provide an exemption from compliance with the standard that states that electrode lead wires and patient cables shall comply with the International Electrotechnical Commission (IEC) standard 601-1 subclause 56.3, paragraph C (1995).

The Southwest Texas State University Department of Physical Therapy is accredited through the Commission on Accreditation of Physical Therapy Education and abides by all requirements related to the safe practice of physical therapy. The Department of Physical Therapy utilizes electrical stimulation devices for educational purposes to teach indications, contraindications, and application of the stimulation. The devices include electrical stimulators used for pain reduction, muscle stimulation, and tissue healing. The physical therapy program utilizes the equipment for educational purposes only; the units are not applied to patients. Students are taught the safe application of electrical stimulation and are always monitored while the devices are in use.

The devices are inspected annually for safe and proper functioning by a company specializing in equipment evaluation. Any equipment deemed unsafe is either repaired or destroyed. Equipment that is no longer needed or used by the department is destroyed. Electrical stimulation units are never sold, donated, or otherwise used outside of the physical therapy program.

The physical therapy program currently has 30 units both portable and tabletop that are used for educational purposes. It is cost-prohibitive to have these devices adapted at this time. Action has been taken by the program to post notices and inform all persons who intend to use the electrical stimulation devices of the potential hazards of using electrode lead wires with unprotected pins. Instruction on the safe method of connecting and disconnecting individuals from devices is provided to all persons using the devices.

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Your consideration in this matter is greatly appreciated. Please feel free to contact me with any questions you may have. I look forward to your response.

Sincerely,

Brenda Boucher, PhD, PT, CHT
601 University Dr. HSC 310A
San Marcos, TX 78666
(512) 245-8426

Southwest Texas State University

601 University Drive San Marcos, Texas 78666-4616

Telephone: 512•245•8351 Fax: 512•245•8736

SWT is a member of the Texas State University System.

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December 19, 2000

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Please add this statement regarding environmental impact as an addendum to a petition dated December 4, 2000 from the undersigned, which pertains to 21 CFR 898 of the FDA. There is no environmental impact statement required for this petition of exemption on electrode lead wire compliance.

Sincerely,

Brenda Boucher, PhD, PT, CHT
601 University Drive HSC 310A
San Marcos, TX 78666
(512) 245-8426

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601 University Drive San Marcos, Texas 78666-4616
Telephone: 512-245-8351 Fax: 512-245-8736
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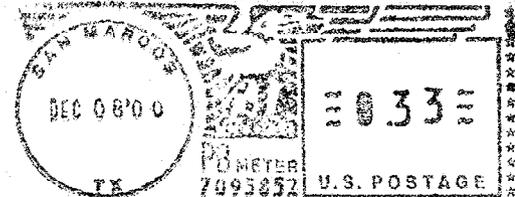


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