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California Energy Commission
(Docket No. 06-AAER-1)
Docket Unit
1516 Ninth Street, Mail Station 4
Sacramento, California 95814-5504

Re: Comments of EBI, L.P. on Proposed Exemptions for Medical Devices: Appliance Standards (Docket No. 06-AAER-1)

Dear Commissioners Pfannenstiel and Rosenfeld:

This firm represents EBI, LP, ("EBI") a pioneering, global leader in electro and biomechanical medicine and one of six strategic business units of Biomet, the fifth largest producer of orthopaedic products worldwide. Located in Parsippany, New Jersey, EBI designs, develops, manufactures and markets products used primarily by orthopaedic medical specialists in both surgical and non-surgical therapy and features an unparalleled line of innovative electrical stimulation and external fixation devices, in addition to a comprehensive line of spinal and orthopaedic support products.[1]

On behalf of EBI, we are writing to support the Commission's proposed amendments to Section 1601(u) of its Appliance Efficiency Regulations as set forth in the Commission's "Express Terms: Proposed Amendments To Appliance Efficiency Regulations," dated February 14, 2006. Specifically, the proposed revisions to Section 1601(u) would exclude "power supplies that are classified as devices for human use under the Federal Food, Drug and Cosmetic Act and require U.S. Food and Drug Administration listing and approval as a medical device." EBI supports the proposed exclusion.

EBI manufactures and sells FDA-regulated electronic bone growth stimulators, cold therapy products, and other devices and implants used in orthopedic medicine. EBI's bone growth stimulators and cold therapy products utilize single voltage external AC to DC power supplies which would be excluded in the Commission's proposed amendment to Section 1601(u).

EBI supports the proposed amendment to Section 1601(u) for a variety or reasons all related to the difficult and time-consuming process of redesigning, safety testing, and obtaining regulatory approval for changes to medical devices.

[1] You can find more information on EBI on the web at www.ebimedical.com.

The proposed exclusion in Section 1601(u) will mean that these devices continue to be available to California medical patients and practitioners. If the exclusion is not approved, converting existing electronic medical would require, at a minimum, the following process:

- Obtaining samples of proposed designs;
- Testing each design for such things as electromagnetic compatibility, interference, transients, safety (fire, temperature and insulation), harmonic flicker, interaction with a control unit, and dielectric breakdown;
- Assuming that the testing is successful, consolidating test results (both in-house and external) into reports to be submitted to the FDA;
- Changing product labeling and package inserts;
- Preparing a Pre-Market Approval (PMA) Supplement for filing with the FDA;
- Submitting the PMA Supplement to the FDA;
- Awaiting FDA approval until received; and
- Redesigning product packaging and carrying cases.

If they could not justify the time, money and resources that would have to be expended if the exclusion is not implemented, given that the market for some products in the State of California is not large, some manufacturers may simply choose not to offer certain devices for sale in California. Thus, without the proposed exclusion in Section 1601(u), the regulations could have the effect of altogether depriving California patients of certain healthcare technologies. Fortunately, the revised language in Section 1601(u) avoids these problems and ensures that California's patients will continue to have access to important medical devices.

Substantively, the potential energy savings to be attained by applying the regulations to medical devices is minimal. EBI's bone healing devices are used only on patients with unhealed fractures and only for a maximum of 400 days. Typically, patients with such devices heal sooner. Once the patient is healed, the product is no longer used. Similarly, EBI's cold therapy device is used only when patients are experiencing pain and swelling.

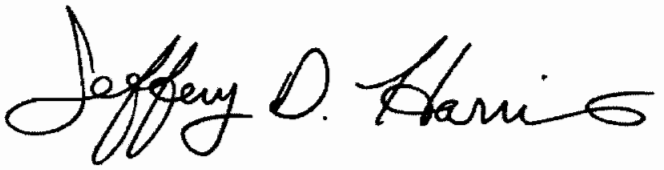
Of course, EBI appreciates the importance of saving energy wherever medically feasible. EBI also understands and appreciates that the medical professionals who use EBI's products prefer that they be effective and efficient, consistent with EBI's mission to develop the technologies, products and services that reduce pain, speed the healing process, and enhance quality of life.

For all the reasons stated above, EBI supports the Commission's proposed amendment to Section 1601(u) of the Regulations.

If you have any questions or comments, please feel free to contact me at (916) 447-2166, and I will make sure that the appropriate EBI representatives are made available to answer your

questions or to discuss energy saving features associated with the EBI's product lines. Thank you for your time and consideration.

Sincerely,



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