

Letters From China

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Docket: [FDA-2011-N-0504](#)

Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

Comment On: [FDA-2011-N-0504-0001](#)

Requirement for Premarket Approval for Cranial Electrotherapy Stimulator

Document: [FDA-2011-N-0504-0053](#)

Yixin Chen - Comment

Submitter Information

Address:

Jiangsu Province, China,

Submitter's Representative: Licensed Clinical Doctor

Organization: Nanjing Brain Hospital

General Comment

August 20, 2011

Nancy K. Stade

Deputy Director for Policy,

Center for Devices and Radiological Health

Food and Drug Administration

5630 Fisher Lane, Room 1061

Rockville, Maryland 20852

Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the Federal Register on August 8, 2011 (76 F.R. 152, p. 48062). As a practitioner who uses CES in my practice, I wanted to share with FDA my own findings on the efficacy and safety of CES.

I am a licensed clinical doctor in China treating children with ADHD(Attention-deficit hyperactivity disorder) and other behavioral or psychological issues. When I get a child who is ADHD or tic disorder my option has been for them to see a psychiatrist who will prescribe medication or inpatient treatment. Many of the parents do not want to take that road so I offer them Alpha-Stim. 60 minutes a day for three weeks transforms their ADHD child into a loving one and everyone is happy. When the therapy is going on, I find that their symptoms were relieved, and it has been a significant improvement in mood. And the results are long lasting.

Thank you for your attention to this matter. Please do not allow access to Cranial Electrotherapy Stimulation to be denied these deserving patients.

Sincerely,

Chen Yixin,
Licensed Clinical Doctor, Vice Professor
Child Mental Health Research Center, Nanjing Brain Hospital .

Attachments

Yixin Chen - Comment, doctor

August 20, 2011

Nancy K. Stade
Deputy Director for Policy,
Center for Devices and Radiological Health
Food and Drug Administration
5630 Fisher Lane, Room 1061
Rockville, Maryland 20852

Re: The Federal Register, Vol. 76, No. 152, pgs. 48062-48070. Proposed Rule: "Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator." [Docket No. FDA-2011-N-0504].

Dear Ms. Stade:

I am submitting this response at the request of the Food and Drug Administration (FDA) in its Proposed Rule for Cranial Electrotherapy Stimulation (CES) issued in the Federal Register on August 8, 2011 (76 F.R. 152, p. 48062). As a general agent in China, I want to share with FDA our own finding of the efficacy and safety of CES.

Alpha-Stim SCS (CES) has been approved as a medical device since 2002 by China FDA. Now there are more than 150 hospitals and psychological institutions are using CES as a safe and effect treatment. CES are more and more widely used in China, and we are licensed to sell online with or without prescription. We have follow-up of the purchased customers. Most of the customers said they felt better, and CES improved their condition, they can go back to society, go back to their work. Besides, we have no doubt of the safety, the discomfort is mild and controllable during the treatment, when the treatment was finished, they felt calm and comfortable. No one has ever been injured and I observed it to be safe and effect. I feel it is important to keep being able to offer this American technology to our customers, especially for pregnant women and children.

Thank you for your attention to this matter. It is my hope that FDA will allow CES to be down-classified to a Class II device as it has proven itself to be both safe and effective.

Sincerely,

Li Dan

NANJING VISH MEDICAL TECHNOLOGY Ltd.

