

# Letters From the Clergy





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Nancy K. Stade  
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5630 Fisher Lane, Room 1061  
Rockville, Maryland 20852

Re: Comments on Alpha-Stim Cranial Electrotherapy Stimulation based on 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).

It is with shock and dismay that I have recently learned of the FDA attempted plans to remove the Alpha-Stim device from the market.

I personally purchased an Alpha-Stim to treat my depression, insomnia, and Post Traumatic Stress Disorder. Although there was plenty of research on the device what influenced me was that it worked. Again and again.

As a faith based counselor and law enforcement chaplain of over twenty years I aquired a second and the a third Alpha-Stim to use with my clients and the results were outstanding.

I used the device on law enforcement officers, soldiers and clients in general with rave reviews and outstanding results.

Yet despite the repeated successful use of the Alpha-Stim worldwide, despite the hundreds of pages of research it seems the FDA wants to label it all "junk science." How can this be? How can the FDA ignore the reports and research let alone the personal successful testimonies of persons who have used the device such as myself.

In addition to bringing this outstanding product to market the management of Alpha-Stim donated a half dozen of these devices for me to take to Haiti following the earthquakes there. And I know of other similar donations they have made to elevate the suffering in other disasters.

Additionally they have joined with my non profit organization the Police Assistance Coalition in making available to families of police officers killed in the line of duty an Alpha-Stim device at no cost to help alleviate their suffering.



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Continued: Re: Comments on Alpha-Stim Cranial Electrotherapy Stimulation based on 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].

Please explain to me why the FDA would attempt to take such a helpful and useful device off the market when so much help has been done for the hurting masses.

Last year I was invited to Ft. Hood to personally witness the successful use of the device on soldier most of whom were suffering physical pain as the result of a deployment injury. Time after time I heard the soldier state that the use of the pain control function of the Alpha-Stim had abated their pain.

I am proud to be a member of a number of prestigious organizations as I take my work with survivors of trauma very seriously.

I am chairman of the Advisory Board of the American Board for Certified Master Chaplains, I am Region 7 Deputy Director of the International Conference of Police Chaplains, I am Master Chief Chaplain for Law Enforcement for Chaplain Fellowship Ministries, I am on the Scientific and Professional Board of the National Center for Crisis Management/ American Academy of Experts in Traumatic Stress.

Additionally I hold a number of board certifications in the area of Homeland Security and trauma work.

I strongly urge the FDA to abandon the idea of attempting to remove Alpha-Stim from the market. Failure to do so will cause so many people to again suffer from the depression, anxiety, insomnia, and physical pain they have had successfully abated by the Alpha-Stim.

As a Faith Based Counselor I urge the FDA to have faith in such a helpful device as Alpha-Stim and allow it to be down-classified to a Class II device because it has proven itself to be both safe and effective in many valid published scientific studies and over 30 years of use.

Sincerely,

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**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 consumer who owns an Alpha-Stim, I wanted to share with FDA my own findings on the device.

I am a retired Navy Chief Hospital Corpsman, Vietnam Veteran and rated at 100% Disabled by the VA with PTSD. Currently, I am a Catholic priest working One on One with Combat Veterans from all Wars and “Military Police Actions.” I first became aware of Cranial Electrotherapy Stimulation while attending the Navy/Marine Corps Combat Operational Stress Control Conference this past Spring in San Diego, CA. During the breaks, I tried out the CES for three days in a row and discovered that it not only helped me sleep more soundly but also helped to lift my Major Depression to a much more tolerable level. I am currently on medications, as prescribed by my VA Psychiatrist and still participate in Group Therapy. I was loaned a CES Device and use it every other day. This has enabled me to function at a more normal level and I have a brighter affect as a result of using this device. I was just assigned to a different Psychiatrist and won't be seeing him until mid December. I will share with him the information brochure and hopefully, he will be able to see the advantage of this device and encourage the VA PCT Clinic to invest in some to use on PTSD patients. It has made a world of difference in my daily living and interactions with others. I have been blessed by being given the opportunity to use the Cranial Electrotherapy Stimulator.

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.

Sincerely,

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