DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 2004

Linda Andre, Director
Committee for Truth in Psychiatry
P.O. Box 1214
New York, NY 10003

Dear Ms. Andre,

Re: Docket No. 2003P-0555

The Center for Devices and Radiological Health of the Food and Drug Administration (FDA) has completed its review of your petition dated December 10, 2003. In your petition you are requesting that the Commissioner of Food and Drugs maintain the electroconvulsive therapy device (882.5849) in class III for all indications.

We apologize for the delay in responding to your petition. After carefully reviewing all relevant information, we have concluded that the agency has no plans to reclassify the electroconvulsive therapy device at this time. If the agency position should change in the future, we will follow proper administrative procedures, which will allow ample public input by any and all interested persons.

If you have any questions about this response, please call Mrs. Myrna Hanna at (301) 827-2971.

Sincerely yours,

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

2003P-0555

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