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~~Committee for Truth in Psychiatry 02N-0434 July 2002 24 11 31~~

Dockets Management Branch (HFA-205)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0434

Dear FDA:

Committee for Truth in Psychiatry is the national organization of persons who have received electroconvulsive therapy (ECT) without being truthfully informed of its nature or long term effects. We believe FDA's decision to withdraw its proposed rule to reclassify the electroconvulsive therapy device is correct, albeit for the wrong reasons. We have opposed the proposed reclassification for the past twenty years on the grounds that ECT has not been shown to be safe. There is substantial evidence that its risks outweigh its benefits. The manufacturers of the devices have never done a single study or submitted any evidence of their device's safety, and FDA has not called for an independent safety study.

However, there is substantial scientific evidence of ECT's longterm harmful effects, in the form of Docket #82P-0316. The docket contains hundreds of report of extensive permanent amnesia, memory disability, and cognitive disability. Our concern is that now that the proposed rule has been withdrawn, the Docket will be closed or disregarded. FDA must not do so as this Docket contains valid scientific evidence that must be considered in any future rulemaking on this device. We know that FDA is considering reclassification, and in doing so it must consider *all* the scientific evidence, not only a "scientific literature" largely written by users of the device.

We believe that the weight of the evidence did not support reclassification in 1983 and twenty years later, the evidence is even stronger that the ECT device belongs in Class III and must remain there for the protection of patients. FDA is highly motivated to reclassify based on pressure from the ECT industry, but it must base its decision on *all* the scientific evidence available to it—and must not disregard the evidence contained in Docket 82P-0316 because the petition is no longer valid.

Sincerely yours,

Linda Andre
Linda Andre, Director

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02N-0434~~

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