DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Noam Hadas
Scientific Laboratory Products LTD
18 Hazfira St.
Tel-Aviv 67779 Israel

Re: Docket No. 2005P-0213

Dear Mr. Hadas:

This letter responds to your petition dated May 16, 2005, submitted under Title 21 of the Code of Federal Regulations Part 5.10, which was filed by the Food and Drug Administration (FDA) as a citizen petition under 21 CFR 10.30, on May 31, 2005.

Your petition requests that FDA change the classification of electroencephalogram (EEG) electrodes currently classified as class II under 21 CFR 882.1320 (Cutaneous electrode), to class I, exempt from premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act. Under 21 C.F.R. 10.30(2)(iii), the agency may issue a tentative response to a citizen petition. The agency is issuing this tentative response because, for the reasons discussed below, the agency is unable to reach a final decision on your petition.

The agency reviews requests for reclassifications of devices under 21 C.F.R. Part 860, Medical Device Classification Procedures. The requirements for a reclassification petition under Part 860 are different from those for a citizen petition, and include requirements for data and information about the device type that is the subject of the reclassification petition. In particular, section 860.123 dictates the form for reclassification petitions as well as the information a device reclassification petition must include. In addition to other requirements, §860.123 requires that all reclassification petitions include a "full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device."

Although you have provided a statement of the reasons why you believe EEG electrodes should be reclassified, your citizen petition does not include other information required by Part 860. Most importantly, your petition fails to supply supporting data to justify a reclassification to class I. Based on the information currently provided in your citizen petition, FDA would likely deny your citizen petition for lack of the information and the fact that the action you are requesting, should be submitted under 21 CFR Part 860. We suggest you withdraw your citizen petition and consider resubmitting a reclassification petition that conforms to the requirements found in 21 CFR § 860.123. You can

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withdraw your citizen petition by submitting a formal withdrawal notice indicating the Docket number (2005P-0213) to:

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
USA.

If you choose not to withdraw this petition, please respond to this interim response so that we can issue a final response. If you have any further questions about this interim response or the reclassification process, please contact Heather Rosecrans at 301-594-1190 x143.

Sincerely yours,

Linda S. Kahan

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