



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 4, 2000

Loretta A. Mooney
Director of Quality Systems
NeuroControl Corporation
8333 Rockside Road, First Floor
Valley View, OH 44125-6104

Dear Ms. Mooney:

Your petition requesting the Food and Drug Administration to allow a variance for electrode lead wires and patient cables was received by this office on 12/01/00. It was assigned docket number 00P-1648/CP 1 and it was filed on 12/04/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

00P-1648

ACK 1