DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 4 2004

Jeanne Keith-Ferris, RN, BSCN
President/Founder, GPDA
GPDA: 5520 Dalhart Hill NW
Calgary, AB
T3A 1S9

Re: 2004-P0091
Dated:

Dear Ms. Keith-Ferris:

This letter is in response to your citizen's petition received on February 24, 2004, and amended on March 16, 2004. On February 24, you requested that the Food and Drug Administration (FDA) transfer approval of the Enterra Therapy™ System from a Humanitarian Device Exemption (HDE) to a Premarket Approval Application (PMA). In your March 16 amendment, you requested that FDA refer your petition to the Gastroenterology and Urology Devices Advisory Panel (GU Panel) to review the efficacy data for the Enterra Therapy™ System and that FDA invite Medtronic Inc. "to begin the process to transfer the Enterra Therapy™ device from a HUD status to PMA status."

We have reviewed the information you have provided and regret to inform you that FDA must deny your petition. Our decision was based on the considerations outlined below.

1. There is no regulatory means of "transferring" approval status. Rather, each type of application must be supported by data and information specifically required by the statute and implementing regulations (section 515 of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. 360e; see also 21 CFR 814.20).

2. The scientific evidence needed to support a PMA approval under section 515 of the Act (21 U.S.C. 360e) differs from that required for HDE approval under section 520(m) of the Act (21 U.S.C. 360j(m)). Whereas an HDE applicant must demonstrate that the device will not expose patients to an unreasonable or significant risk of illness or injury and that the probable benefit from the use of the device outweighs the risk from its use, a PMA applicant must demonstrate reasonable assurance of safety and effectiveness of the device. After a preliminary review of the information you have provided, the agency does not believe that your summary of the clinical literature is sufficient or adequately

complete to make scientific conclusions regarding the safety and effectiveness of the device in support of PMA approval.

3 Because no regulatory mechanism exists to grant the relief requested the agency must deny the request to convene the Gastroenterology and Urology (GU) Devices Advisory Panel specifically to discuss this issue. Even in the case of positive feedback from the Panel, the agency would still be unable to make the changes in approval status without the required information.

Although the agency is unable to grant the specific relief requested in your petition, other avenues exist by which expanded coverage for Enterra Therapy™ may be sought. As you are aware, nothing precludes Medtronic, Inc. from seeking PMA approval for this device; we therefore suggest you bring your data and concerns to the attention of the company. Furthermore, FDA would like to remind you that denial of this petition does not preclude your organization from making a presentation to the GU Panel during an open public session of a scheduled meeting. For more information on future GU Panel meeting dates, you may contact Jeffrey Cooper, D.V.M., Executive Secretary, at 301-594-1220.

FDA understands that part of your concern and reason for submitting your petition relates to the failure of health insurance providers to allow for reimbursement for use of these devices. Below, we have provided additional information on the HDE approval process that may help you obtain insurance coverage for the device.

The HDE statutory provision states, "To the extent consistent with the protection of public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States" (section 520(m) (1) of the Federal Food, Drug and Cosmetic Act (the act)). Without the HDE provision, an unmet medical need would exist for these small patient populations. (See section 520(m)(2)(B) of the act and the clarification of this provision in 101 S. Rept. 513, at 41, 1990.)

In adding the HDE provision to the act, Congress recognized that conducting scientifically valid clinical investigations to demonstrate effectiveness in such small patient populations would be very difficult. Therefore, a clinical trial is not required to be conducted before a humanitarian use device can be approved for marketing through an HDE. Rather, the HDE provision provides for the approval and commercial distribution of a humanitarian use device based on appropriate pre-clinical and clinical information. HDE applicants often use clinical information from published literature, data from small clinical studies, or data gathered from marketing experience or clinical studies conducted outside the United States to support approval.

The Summary of Safety and Probable Benefit, which summarizes the information included in the HDE application on which FDA based its approval decision, for the

Medtronic Enterra™ Therapy System is available on the internet at http://www.fda.gov/cdrh/pdf/h990014b.pdf.

FDA considers the Medronic Enterra™ Therapy System to be a legally marketed device under the HDE provision. An investigational device exemptions application (See 21 CFR Part 812 Investigational Device Exemptions), which would be required for "experimental" or "investigational" use, is not required for the use of this device for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. Furthermore, the act does not require informed consent from individuals treated with a device approved under the HDE provision as would be the case with an investigational device.

FDA handles approved HDE applications in the same manner as approved PMAs. That is, FDA provides a copy of the approval order for an HDE application to the Office of Coverage Policy of the Centers for Medicare and Medicaid Services (CMS), just as we do for an approved PMA. CMS's criteria for determining whether to cover a medical device are not based solely on whether FDA has approved the device for marketing. Detailed information about the process for requesting a national coverage determnination from CMS appears at 68 *Federal Register* 55634 (September 26, 2003).
If you have any questions regarding this letter, you may contact Joseph Sheehan, Chief of the Regulations Staff, at 301-827-2974.

Sincerely,

Linda S. Kahan

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