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Charles H. Swanson
Vice President Chief Regulatory Officer

December 19, 2002

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, Maryland 20852

Subject: Docket No. 02D-0325: Medical Devices Made with Polyvinylchloride (PVC) Using the Plasticizer di-(3-Ethylhexyl) phthalate (DEHP); Draft Guidance for Industry and FDA

Dear Sir/Madam:

This letter is being written to support the comments recently provided by AdvaMed, which are enclosed for your reference, on the subject document. As found in the FDA Safety Assessment, there are no studies that scientifically demonstrate any toxic or carcinogenic effect of DEHP on humans. Based on this information, Medtronic believes FDA's recommendations are too broad to warrant a design requirement, labeling or marking for all medical device products that contain PVC/DEHP.

Patient safety is of primary importance to Medtronic and we have established robust systems to meet high product quality standards. If you have any questions, please do not hesitate to contact me at (763) 505-2562.

Sincerely,

Charles H. Swanson

CHS:kls:dehpltrFDA12-2002

Attachment (1)

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