United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

July 18, 2005

VIA FACSIMILE: (301) 827-1960
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Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

The Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs, among other matters. Accordingly, the Committee is responsible to the more than 80 million Americans who receive health care coverage under those programs, including payment for medical devices.

Today, Guidant Corporation (Guidant) issued a press release entitled, "Guidant Initiates Worldwide Physician Communications Regarding Important Safety Information and Corrective Action about Certain Pacemakers." Guidant's action today, which the company says the Food and Drug Administration (FDA) may classify as a recall, comes on the heels of recalls for several other Guidant devices, specifically Implantable Cardiac Defibrillators.

As Chairman of the Committee, I request that the FDA provide the Committee with copies of the past five annual postapproval reports—required under 21 C.F.R. 814.84—for all pacemakers and defibrillators associated with Guidant's device warnings, issued on May 25, June 17, June 24 and July 18, 2005. In addition, it is my understanding that the FDA does not presently make all device manufacturers' annual postapproval reports publicly available, despite the fact that the reports contain important performance data. Among other detailed information, pacemaker and defibrillator manufacturers must report to the FDA the number of patient deaths, analyses of failure mechanisms, and other safety and effectiveness issues. Given the importance of such information to health care providers and the scientific community, state why the FDA should not proactively post such information in the FDA's electronic reading room. In addition, describe in detail the FDA's disclosure policy with respect to post approval-related documents for devices, including but not limited to pacemakers and defibrillators.

Thank you in advance for having your staff coordinate with my staff about this letter by July 22, 2005. I would appreciate your response by August 3, 2005, unless it is available sooner. Any questions or concerns should be directed to . All formal correspondence should be sent electronically in PDF searchable format to and original by U.S. mail. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley
Chairman