DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 29, 2003

Eric S. Fain, M.D.
Senior Vice President, Clinical Engineering and Regulatory Affairs
St. Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91342

RE: Docket No. 02P-0089

Dear Dr. Fain,

This is in response to your petition dated February 26, 2002 and filed by the Food and Drug Administration (FDA) on March 5, 2002. We had previously issued you an interim response on September 11, 2002.

In your petition, you requested that FDA allow electronic labeling to be an acceptable media to meet the labeling requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq. (the Act), for St. Jude's Model 3500/3510 programmer with Model 3307, v2.4a programmer software, PMA numbers P880086, P830045, and P910023, a programmer/computer intended to be used by physicians to interact with an implanted pulse generator at the time of implantation and on follow-up visits.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA), P.L. 107-250, was signed into law October 26, 2002. Among other provisions, section 206 of MDUFMA amended section 502(f) of the Act (21 U.S.C. 352(f)) to provide that labeling for prescription devices intended for use in health care facilities may be provided solely by electronic means, so long as users may request the labeling in paper form and such labeling is promptly provided to requestors without additional cost. Section 206 of MDUFMA required that electronic labeling continue to satisfy any legal requirements that apply to device labeling in general. Manufacturers electing to provide electronic labeling must ensure that it is not false or misleading in any particular and are expected to meet all other applicable regulatory requirements, such as those contained in 21 CFR Part 801.

New section 502(f) was effective upon enactment. Our records indicate that, as authorized by section 515(d)(1)(B)(ii) of the Act, the PMA orders (P880086, P830045, and P910023) condition approval of the St. Jude programmer/computer on the device being restricted to prescription use, in accordance with 21 CFR 801.109. Consequently, you may issue labeling for this device in electronic form, provided that you adhere to the other requirements in new section 502(f).

If you have any questions about this response, please contact Joseph M. Sheehan of our Regulations Staff at (301) 827-2974.

Sincerely yours,

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