DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 1 1 2002

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

Ref: FDA Docket No. 02P-0089

Dear Dr. Fain:

This letter responds to your citizen petition on behalf of St. Jude Medical requesting that The Food and Drug Administration (FDA) permit the use of electronic labeling by "amending the regulation of the labeling as stated in Section 201(m) in the Federal Food, Drug and Cosmetic Act to allow electronic labeling to be an acceptable media to meet this requirement." You ask us to permit the use of the electronic copy of the labeling, which resides in the programmer/computer that is required to use the implanted device. This electronic copy would be provided in lieu of a printed hardcopy of the paper manuals, but the users would have an option to obtain the paper manuals at their request.

The FDA commends efforts to provide clear, convenient, and user-friendly labeling. To this end, the FDA is continuing to review your request and other similar proposals to determine whether, and under what conditions, electronic labeling may be employed to provide information required in the labeling of medical devices. We will send you a final response to your petition after we complete our review of this issue.

If you have any questions, 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

02P-0089

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