ST. JUDE MEDICAL

Cardiac Rhythm
Management Division

February 26, 2002

Dockets Management Branch
FDA, DHHS
Room 10-61
5630 Fishers Lane
Rockville, Maryland 20857

RE: **Citizen Petition**
Electronic labeling for computer-based devices
Model 3500/3510 programmer with Model 3307, v2.4a programmer software
PMA P880086/S84, P830045/S77, P910023/S54

Dear Sir/Madame:

St. Jude Medical is submitting an original and three copies of a Citizen Petition in accordance with 21 CFR Part 10.30. This petition is requesting 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. Currently under Section 201(m), the definition of labeling states that labels and labeling are required to be of written, printed, or graphic matter. SJM is proposing to eliminate mandatory shipping of paper copies of the programmer software reference manuals for this and future software versions. In this particular application (i.e., the electronic copy of the labeling residing on the programmer/computer that is required to use the implanted device), physicians have better access to an electronic copy of the labeling than they would a paper copy.

Eric S. Fain, M.D.
Senior Vice President, Clinical Engineering and Regulatory Affairs

02P-0089

CP 1 SP5

Citizen Petition

The undersigned, submits this petition to amend Section 201(m) of the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision, for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10).

A. Action Requested

St. Jude Medical (SJM) is requesting amending the definition of labeling as stated in Section 201(m) of the Federal Food, Drug, and Cosmetic Act and proposing that the labeling regulation be modified to allow for electronic labeling. SJM requests the following regulation be amended in the specific case of a programmer/computer that is required to be used to interact with an implanted pulse generator [amended language in underlined type]:

Section 201(m)

"Labeling" includes all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. In addition "labeling" may include electronic matter in specific applications as defined by FDA.

B. Statement of Grounds

At the suggestion of FDA and based on the FDA letter dated November 6, 2001 (provided as Appendix 1) SJM is submitting a citizen's petition to address the use of electronic labeling for computer based devices, such as our programmers. The programmer is a personal computer (PC), which a physician must use to interact with the implanted device (i.e. to interrogate or program the implanted device at the time of implantation, subsequent testing and at every follow up visit). The On Screen Manual feature allows for availability of the programmer manuals on screen. We believe that in this particular application (i.e., the electronic copy of the labeling residing on the programmer/computer that is required to use the implanted device), physicians have better access to an electronic copy of the labeling than they would a paper copy. This improves physician accessibility to the programmer manuals, especially in follow-ups of already implanted devices, where the paper manuals may be kept in a different location. Having the manuals available electronically on the programmer ensures that the labeling is always available when the product is in use. It also ensures that the latest version of the labeling that is associated with the currently loaded programmer software is always available and accessible. This is an improvement over paper manuals, as older versions of the manuals will be automatically obsolete and replaced when a new software version is loaded on the programmer. We would also make available paper manuals at customer request.

Currently the definition of labeling in Section 201(m) of the Federal Food, Drug, and Cosmetic Act states that labels and labeling are required to be written, printed, or graphic matter. At this time the Act does not take into consideration the option of electronic labeling. SJM would like for CDRH to review and modify the regulation to allow for the use of electronic labeling in the specific application of a programmer/computer that supports an implanted device.

In addition electronic labeling is under consideration as part of the HR 3580 Medical Device Amendments of 2001 reform bill, which would amend Section 201(m) labeling guidance to add: "For purposes of providing adequate directions for use, labeling may also include written, printed, or graphic matter, which is displayed by electronic means and is intended as labeling by the person responsible for labeling an article".

C. Environmental Impact

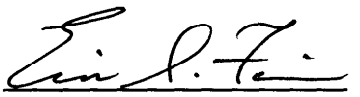
Electronic programmer manuals would greatly reduce consumption of paper. Last year almost 30,000 sizeable paper programmer manuals (approximately 400 pages per manual) for a total of 1,200,000 pages were printed and distributed by SJM in the US.

D. Economic Impact

Currently a printed hardcopy of the programmer manuals is included with each software upgrade kit. Electronic manuals would allow for a more paperless system, which would reduce consumption of paper. Last year almost 30,000 sizeable paper programmer manuals were printed and distributed at a cost of almost one million dollars.

E. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.



Eric S. Fain, M.D.
Senior Vice President, Clinical Engineering and Regulatory Affairs
St. Jude Medical, CRMD
15900 Valley View Court
Sylmar, CA 91342
408/522-6188

Appendix 1
FDA Letter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

NOV - 6 2001

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

Re: Model 3307 V2.4a Programmer Software
P880086/S84, P830045/S77, and P910023/S54

Dear Dr. Fain:

This is in response to your August 31, 2001, letter and copy of the PMA submission for the above referenced device. Your letter requests that the labeling for your device be an on-line help feature rather than a paper copy.

The definition of labeling appears in Section 201(m) of the Federal Food, Drug, and Cosmetic Act (the Act), and it states that labels and labeling are required to be of written, printed, or graphic matter. The Act does not take into consideration electronic labeling, at this time. The Center for Devices and Radiological Health (CDRH) is required to operate under the provisions and limitations of the Act.

The concept of electronic labeling makes sense for computer-based devices such as yours and CDRH does recognize the need to further study the issue of electronic labeling. As such, we have established a task force to study the electronic labeling issue. No recommendations, however, have yet issued from the task force.

In response to Section 201(m), we drafted a labeling guidance document. In it, the glossary lists the terms "communication medium" or "communication media". These terms are intended to refer to other printed materials such as charts or graphs. Based on the definition of labeling in the Act, and the interpretation provided by the guidance document, we continue to support that written labeling is required. Consequently, firms cannot replace the printed material required by the Act with CD-ROMs. Firms may provide CD-ROMs, or other electronic substitutes along with the printed material, but that may not serve as a substitute for the printed material required by the Act.

We believe that your interest in establishing user friendly electronic labeling and the elimination of printed manuals are important issues. These issues, however, extend beyond our jurisdiction. You may consider taking advantage of filing a Citizen's petition as described in 21 Code of Federal Regulations (CFR) Part 10.30.

If you require further clarification, you may contact Mary Ann Fitzgerald, Consumer Safety Officer, Division of Enforcement III, by telephone at (301) 594-4648, or you may write to her at the address on this letterhead.

Sincerely yours,

Harold A. Pellerite
Assistant to the Director
Office of Compliance
Center for Devices and
Radiological Health

HOW TO PETITION THE FDA

Anyone may request or petition FDA to change or create an Agency policy or regulation under 21 CFR Part 10.30. If you believe this type of action is necessary, direct your request to FDA's Dockets Management Branch http://www.fda.gov/ohrms/dockets/. When submitting a petition, keep these points in mind:

- Clearly state what problem you think the Agency needs to address.
- Propose specifically what the Agency's action should be. Your proposal should be based on sound, supportable facts.
- Submit the petition, an original and three (3) copies, unless otherwise stipulated in the Federal Register announcement, to:

Food and Drug Administration
Dockets Management Branch
Room 10-61
5630 Fishers Lane
Rockville, MD 20857
(301) 827-6860

FDA carefully considers every petition and must respond within 180 days by either approving or denying it, or providing a tentative response indicating why FDA has been unable to reach a decision. If FDA approves the petition, it may be published in the Federal Register. Your petition could eventually be incorporated into Agency policy. An example showing how to prepare a citizen's petition follows:

Petition Content and Format

(Date) _____
Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 10-61, 5630 Fishers Lane, Rockville, MD 20857.
CITIZEN PETITION
The undersigned submits this petition under _____ (relevant statutory sections, if known) of the _____ Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to _____(issue, amend, or revoke a regulation or order to take or refrain from taking any other form of administrative action).

A. ACTION REQUESTED

1. . If the petition requests the Commissioner to issue, amend or revoke a regulation, give the exact wording of the existing regulation (if any) and the proposed regulation or amendment requested.

2. . If the petition requests the Commissioner to issue, amend or revoke an order, include a copy of the exact wording of the citation to the existing order (if any) and the exact wording requested for the proposed order.
3. . If the petition requests the Commissioner to take or refrain from taking any other form of administrative action, state the specific action or relief requested.

B. STATEMENT OF GROUNDS
Include a well organized statement of the factual and legal grounds upon which the petition is based. Opposing views known to the petitioner should be presented.

C. ENVIRONMENTAL IMPACT STATEMENT
Give an environmental impact analysis report in the form specified in 21 CFR, Part 25.1(g), except for the types of actions specified in 21 CFR, Part 25.1(d).

D. ECONOMIC IMPACT STATEMENT
The following information is to be submitted only when requested by the Commissioner following review of the petition: a statement of the effect of the requested action on 1) cost (and price) increases to industry, government, and consumers; 2) productivity of wage earners, businesses, or government; 3) competition; 4) supplies of important materials, products, or services; 5) employment; and 6) energy supply or demand.

The undersigned certifies that, to the best of his/her knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

_____ _____

(Signature) Name of Petitioner

_____

(Mailing Address)

_____

(Phone)