



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

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June 6, 2000

Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane, Room 10-61  
HFA-305  
Rockville, MD 20852

Re: Docket No. 00D-0785

Dear Ms. Silberberg:

CDRH's Division of Small Manufacturers, International and Consumer Assistance (DSMICA) Consumer Staff appreciates the opportunity to review the excellent Draft Guidance on Medical Device Patient Labeling. Here are our comments:

1. Throughout the document, state that the manufacturer should consider the end-user's need for patient labeling in languages other than English.
2. On page 9 in the section on Distributing the Medical Device Patient Labeling include a bullet on the importance of the patient having sufficient time to both read and absorb the risk information and to do additional research. The time element is important in particular for patients and their caregivers who are under stress due to a health condition; and, therefore, have difficulty comprehending risk information.
3. On pages 12 and 13 under the Content of Risk Messages section, change the bullet that states "should acknowledge uncertainties" to "should acknowledge uncertainties including lack of currently available scientific knowledge" and move this bullet toward the beginning of the list. A statement such as this is also appropriate for other sections in this document.
4. On page 19 in the warranty section suggest that patients receiving an implanted device be provided with a card listing the manufacturer of the implant, date implanted, model #, lot #, size, type, etc. Include this same suggestion at the end of the second paragraph under User Assistance on page 20.

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5. On page 20 in the User Assistance Information section as well as other sections, provide information on how the patient can report health problems associated with the device to the agency via FDA's MedWatch 800 number or find this information on the FDA Web Site and also report device malfunctions/failures to manufacturers via their 800 numbers and Web Sites.
6. Also on page 20 in the User Assistance Information section recommend to manufacturers that they include patient labeling for their medical devices on their Web Sites.
7. In multiple sections throughout the document state that a list of materials in both temporary and permanent/absorbed medical devices is needed, so that patients with hypersensitivities can easily identify their risks, e.g., petroleum in temporary heart monitoring wires, silicone coatings and latex components.
8. If hypersensitivity to a material has not been sufficiently studied and/or is not scientifically documented clearly state that information. In addition, if there is a potential risk the patient is taking on behalf of his/her children, e.g., breast implants for women and pectoral implants in men clearly state that information. In this way both physicians and patients will be able to clearly understand that risks to the unborn are not known.
9. In pertinent sections in the document, state the expected life/failure/rupture rates e.g., eight years for breast implants, pacemaker batteries, etc.
10. In the Warnings and Precautions section, state any risks where a device can cause injury to a patient, e.g., temporary monitoring wires that are not removed by the surgeon, metal breast expander shunts that may cause a distortion/injury with MRI.

We thank you for the opportunity to comment on this document. We believe the document is an important step forward in the Center's goal to keep patients informed.

If you have any questions, please contact me at 301-443-7491 ext. 144.

Sincerely,



Barbara P. Stellar, LCSW-C  
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DSMICA, Consumer Staff  
FDA/CDRH/OHIP

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Public Health Service  
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