

patients are ready to activate the device, and how to evaluate, and how often to evaluate, proper functionality and placement. The directions should instruct caregivers to specifically question patients prior to surgery for any history of allergic reaction to any of the device materials or filling agents. Troubleshooting procedures should be completely described. The directions for use should incorporate the clinical experience with the implant, and should be consistent with those provided in other company-provided labeling.

The labeling should include both implant and explant forms to allow the sponsor to adequately monitor device experience. The explant form should allow collection of all relevant data, including the reason for the explant, any complications experienced and their resolution, and any action planned (e.g., replacement with another implant).

Patient labeling must be provided which includes the information needed to give prospective patients realistic expectations of the benefits and risks of device implantation. Such information should be written and formatted so as to be easily read and understood by most patients and should be provided to patients prior to scheduling implantation, so that each patient has sufficient time to review the information and discuss it with his or her physician(s). Technical terms should be kept to a minimum and should be defined if they must be used. Patient information labeling should not exceed the seventh grade reading comprehension level.

The patient labeling should provide the patient with the following information: (1) The indications for use and relevant contraindications, warnings, precautions and adverse effects/ complications should be described using terminology well known and understood by the average layman; (2) the anticipated benefits and risks associated with the device must be provided to give patients realistic expectations of device performance and potential complications. The known, suspected and potential risks of device implantation should be identified and the consequences, including possible methods of resolution, should be described; (3) alternatives available to the use of the device, including less invasive treatments, should be identified, along with a description of the associated benefits and risks of each. The patient should be advised to contact his physician for more information on which of these alternatives might be appropriate given his specific condition; (4) instructions for how to use the

device must be provided to the patient. This information should include the expected length of recovery from surgery and when to attempt activation following implantation, whether and how often the device should be periodically cycled (if applicable), warnings against certain actions that could damage the device, how to identify conditions that require physician intervention, who to contact if questions arise, and other relevant information; (5) the fact that the implant should not be considered a "lifetime" implant must be emphasized. Where possible, the patient labeling should provide information on the approximate number of revisions necessary for the average patient, and indicate the average longevity of each implant so patients are fully aware that additional surgery for device modification, replacement, or removal may be necessary. This information must be supported by the clinical experience (i.e., not merely bench studies) with the implant or by published reports of experience with similar devices.

The physician's labeling should instruct the urologist or implanting surgeon to provide the implant candidate with the patient labeling prior to surgery to allow each patient sufficient time to review and discuss this information with his physician(s).

The adequacy and appropriateness of the instructions for use provided to physicians and patients should be verified as part of the clinical investigations.

Applicants should submit any PMA in accordance with FDA's "Pre-market Approval (PMA) Manual." The manual is available upon request from the Division of Small Manufacturers Assistance (address above).

### III. Comments

Interested persons may, on or before June 15, 1995, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Those wishing to make comments are encouraged to discuss all aspects of the proposed findings regarding the following topics:

(1) Degree of risk, illness, or injury associated with the use of the implanted

mechanical/hydraulic urinary continence device;

(2) Laboratory, animal, and human studies required in a PMA for the device in order to assess its safety and effectiveness;

(3) Feasibility of these studies within the time permitted by the act, etc.; and

(4) Benefits to the public from the use of the device.

The comments must discuss in detail, for example, the reasons why important new information on the safety and effectiveness of the device could not feasibly be submitted within the time permitted, or why animal studies may not be available to assess long-term effects such as connective tissue disorders, or that carefully designed epidemiological studies may not be available to evaluate the long-term silicone related illnesses, etc.

The Center for Devices and Radiological Health staff are available to provide guidance to manufacturers on any proposed laboratory, animal, or epidemiological studies needed in a PMA.

### IV. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the implanted mechanical/hydraulic urinary continence device is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by March 2, 1995.

The agency advises that to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the implanted mechanical/hydraulic urinary continence device is submitted, the agency will, by April 17, 1995, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the