

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0071]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Penile Rigidity Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices.” This draft guidance document describes a means by which external penile rigidity devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify external penile rigidity devices into class II with special controls. The proposed rule also announces FDA’s intent to exempt external penile rigidity devices from premarket notification requirements. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by [*insert date 90 days after date of publication in the **Federal Register***].

ADDRESSES: Submit written requests for single copies on a 3.5” diskette of the draft guidance document entitled “Class II Special Controls Guidance Document: External Penile Rigidity Devices” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for

Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Janine Morris, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2194.

SUPPLEMENTARY INFORMATION:

I. Background

At a public meeting held on August 7, 1997, the Gastroenterology-Urology Advisory Panel (the Panel) recommended that external penile rigidity devices be classified into class II. The Panel identified special controls as labeling recommendations with specific information for each of the devices. This draft guidance document supports the classification of external penile rigidity devices into class II. The guidance document will serve as the special control for these devices, if the proposed rule becomes final. Following the effective date of a final rule classifying the devices, a manufacturer intending to market external penile rigidity devices, who addresses the issues covered in the special control guidance before introducing its device into commercial distribution in the United States, will be able to market its device without

being subject to the premarket notification requirements of section 510(k) of the Federal Food, Drug and Cosmetic Act. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. FDA may not implement the guidance until the agency completes notice and comment rulemaking to classify the devices.

The draft guidance identifies the risks to health and serves as a special control that, when followed and combined with the general controls, addresses the risks associated with this type of generic device.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on external penile rigidity devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Class II Special Controls Guidance Document: External Penile Rigidity Devices" by fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1231) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular

basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The labeling provisions addressed in the draft guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to identified with the

docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 4, 2004.

Beverly Chernaik Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

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