SUPPLEMENTARY INFORMATION:
I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360d) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see Bell v. Goddard, 366 F.2d 177, 181 (7th Cir. 1966); Ethicon, Inc. v. FDA, 762 F. Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in “medical science” (Upjohn Co. v. Finch, 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the “new information” to support reclassification under section 513(f)(3) must be “valid
scientific evidence,” as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, e.g., General Medical Co. v. FDA, 770 F.2d 214 (D.C. Cir. 1985); Contact Lens Mfrs. Assoc. v. FDA, 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the “valid scientific evidence” upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA (see section 520(c) of the FD&C Act [21 U.S.C. 360j(c)]. Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

On December 4, 2017, FDA published a proposed order in the Federal Register to reclassify the device (82 FR 57174) (the “proposed order”). The period for public comment on the proposed order closed on February 2, 2018. FDA received and has considered 78 comments on the proposed order, as discussed in section II.

II. Comments on the Proposed Order and FDA Response

A. Introduction

FDA received 78 public comments in response to the December 4, 2017, proposed order. These comments originated from individual consumers, academia, healthcare professionals, healthcare associations, local governments, and industry. The overwhelming majority of commenters supported the proposed reclassification, name change, and the general effort to increase patient access to single-use condoms.

We describe and respond to the comments in section B, below. The order of response to the commenters is purely for organizational purposes and does not signify the comment’s value or importance nor the order in which comments were received. Certain comments are grouped together under a single number because the subject matter is similar.

B. Description of Comments and FDA Response

(Comment 1) Several commenters supported the reclassification and name change, but did not think a contraceptive effectiveness study should be required as a special control. These commenters believe that an acute failure modes study would be sufficient to ensure the safety and effectiveness of single-use internal condoms. The commenters indicated that requiring a contraceptive effectiveness study is burdensome and that the contraceptive effectiveness rate of a previously approved internal condom (FC1 Female Condom) should be leveraged in lieu of this special control. Another commenter suggested that single-use internal condoms be evaluated based on data from an acute failure modes study because this is the clinical evidence used to support clearance of male condoms made of synthetic materials. Finally, a different commenter agreed with FDA that there are unique considerations for the female condom, and that FDA should carefully consider each single-use internal condom to determine the appropriate method for clinical validation. The commenter noted that the majority of clinical studies published worldwide are conducted using male condoms, and that analysis by FDA, National Institutes of Health, and the Centers for Disease Control and Prevention re-confirmed the safety and effectiveness of male condoms. This commenter recommended that FDA consider developing a medical device development tool to find less burdensome ways of evaluating internal condom effectiveness using biomarkers. (Response 1) While the probable risks to health and risk mitigations are similar between male and single-use internal condoms, the failure modes are not the same between these two types of condoms. Male condoms have failure modes from slippage and breakage, while single-use internal condoms have failure modes that include slippage, breakage, misdirection, and invagination. FDA believes that a contraceptive effectiveness study is necessary to mitigate the risk of an undesired pregnancy because internal condoms have distinct design features from male condoms (e.g., internal and external retention mechanisms) and from other internal condoms that can only be evaluated through a contraceptive effectiveness study. Accordingly, FDA believes that the clinical evidence from male condoms and other internal condoms cannot be leveraged to mitigate the risk of undesired pregnancy for an individual single-use internal condom. The contraceptive effectiveness rate of an individual internal condom is important because internal condoms are intended for the prevention of pregnancy, and this contraceptive effectiveness rate is important for consumers when deciding which method of contraception is most appropriate for them. FDA is not aware of any information, and none was provided to the docket, supporting that a biomarker method could be used in lieu of a contraceptive effectiveness study.

(Comment 2) One commenter generally agreed with FDA’s proposed reclassification, name change, and the proposed special controls for single-use internal condoms. This commenter stated that, in addition to FDA’s proposed special controls, a pre-clearance good manufacturing practices (GMP) inspection should be required under section 513(f)(5) of the FD&C Act. (Response 2) FDA may withhold 510(k) clearance under section 513(f)(5) of the FD&C Act if there is a substantial likelihood that failure to comply with GMPs will potentially present a serious risk to human health. FDA does not believe the threshold for pre-clearance GMP inspections is met for single-use internal condoms. Single-use internal condoms will be required to comply with GMPs under the quality system regulation per 21 CFR part 820 that will, in part, mitigate the identified probable risks to health. FDA believes that the special controls identified in this final order, in addition to general controls, including compliance with GMPs, will provide reasonable assurance of safety and effectiveness for single-use internal condoms.

(Comment 3) Multiple commenters requested that FDA not change contraceptive coverage policies for single-use internal condoms. (Response 3) Contraceptive coverage policies by private insurance payers and the Centers for Medicare & Medicaid Services are outside the scope of FDA’s reclassification process. FDA is required to classify devices based on the regulatory controls necessary to provide reasonable assurance of device safety and effectiveness. FDA believes that sufficient information exists to establish special controls that, in addition to general controls, can provide reasonable assurance of safety and effectiveness for single-use internal condoms.
FDA has determined that premarket notification is necessary to provide reasonable assurance of safety and effectiveness of single-use internal condoms, and therefore, this device type is not exempt from premarket notification requirements.

The device is assigned the generic name single-use internal condom, and it is identified as an OTC sheath-like device that lines the vaginal or anal wall and is inserted into the vagina or anus prior to the initiation of coitus. At the conclusion of coitus, it is removed and discarded. It is indicated for contraception and/or prophylactic (preventing the transmission of sexually transmitted infections) purposes.

Under this final order, the single-use internal condom is an OTC device. OTC devices must bear adequate directions for lay use as outlined in 21 CFR 801.5. Under 21 CFR 807.81, the device would continue to be subject to 510(k) requirements.

IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 820 have been approved under OMB control numbers 0910–0073; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 884 is amended as follows:
§ 884.5340 Single-use internal condom.

1. The authority citation for part 884 continues to read as follows:


2. Amend § 884.5330 by revising the section heading and paragraph (a) to read as follows:

§ 884.5330 Multiple-use female condom.

(a) Identification. A multiple-use female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic (preventing the transmission of sexually transmitted infections) purposes.

(b) Classification. Class II (special controls). The special controls for this device are:

(1) Clinical performance testing must evaluate the following:

(i) Rate of clinical failure of the device and rate of individual failure modes of the device based on an acute failure modes study evaluating the intended use (vaginal and/or anal intercourse); and

(ii) Cumulative pregnancy rate when using the device based on a contraceptive effectiveness study (when the device is indicated for vaginal intercourse).

(2) Viral penetration testing must demonstrate the device is an effective barrier to sexually transmitted infections.

(3) Nonclinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be evaluated:

(i) Mechanical testing must demonstrate the device can withstand forces under anticipated use conditions, include evaluation of tensile, tear, and burst properties of the device; and

(ii) Compatibility testing with personal lubricants must determine whether the physical properties of the device are adversely affected by use of additional lubricants.

(4) The device must be demonstrated to be biocompatible.

(5) Shelf-life testing must demonstrate that the device maintains its performance characteristics and the packaging of the device must maintain integrity for the duration of the shelf-life.

(6) Labeling of the device must include:

(i) Contraceptive effectiveness table comparing typical use and perfect use pregnancy rates with the device to other available methods of birth control;

(ii) Statement regarding the adverse events associated with the device, including potential transmission of infection, adverse tissue reaction, and ulceration or other physical trauma;

(iii) Expiration date; and

(iv) Statement regarding compatibility with additional types of personal lubricants.


Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2018–0836]

Drawbridge Operation Regulation; Newark Bay, Newark, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Lehigh Valley Bridge across the Newark Bay, mile 4.3, at Newark, New Jersey. The deviation is necessary to replace bridge timber on the lift span. The Lehigh Valley Bridge shall remain in the closed position from 6 a.m. on October 14, 2018 to 6 p.m. on October 15, 2018; from 6 a.m. on October 21 to 6 p.m. on October 22, 2018; and from 6 a.m. on October 28, 2018 to 6 p.m. on October 29, 2018. Should inclement weather occur, the following rain dates may be used: (a) From 6 a.m. on November 4, 2018 to 6 p.m. on November 5, 2018; or (b) from 6 a.m. on November 11, 2018 to 6 p.m. on November 12, 2018.

The waterway is transited by recreational and commercial vessels. Coordination with known waterway users has indicated no objection to the closure. Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.


C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

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