it meets the criteria for a qualified investment set forth in 12 CFR part 25, the bank may include a brief statement to that effect in its letter of self-certification.

* * * * *

(b) * * *

(3) If the bank wants the OCC to consider the investment during an examination under the CRA and to determine whether it meets the criteria for a qualified investment set forth in 12 CFR part 25, the bank may include a brief statement to that effect in its investment proposal.

* * * * *

§ 24.6 [Amended]

5. In § 24.6, paragraph (b)(1) is amended by adding an ''or'' at the end, paragraph (b)(2) is removed, and paragraph (b)(3) is redesignated as paragraph (b)(2).

Dated: May 27, 1999.

John D. Hawke, Jr.,

Comptroller of the Currency.

[FR Doc. 99–14754 Filed 6–9–99; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 99N–1309]

Obstetrical and Gynecological Devices; Proposed Classification of Female Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the preamendments female condom intended for contraceptive and prophylactic purposes. Under this proposal, the preamendments female condom would be classified into class III (premarket approval). The agency is publishing in this document the March 7, 1989, recommendations of FDA's Obstetrics-Gynecology Devices Panel (the Panel) regarding the classification of this device. After considering public comments on this classification proposal, FDA will publish a final rule classifying this device. This action is being taken to establish regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device.

DATES: Written comments by Septmeber 8, 1999. See section IV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies on a 3.5'' diskette of the draft guidance entitled ''Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases, April 4, 1990'' to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 401–443–8818. In order to receive this draft guidance via your fax machine, call the CDRH Facts-On-Demand (FOD) System at 800–899–0381 or 301–827–0111 from a touch-tone-telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (384) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

A. Classification of Medical Devices

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on 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).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendations for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final rule under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and regulations, FDA consulted with the Obstetrical and Gynecological Device Classification Panel regarding the classification of this device. This panel was subsequently terminated, rechartered, and renamed the Obstetrics-Gynecology Devices Panel (the Panel).

B. Regulatory History of Female Condoms

In the **Federal Register** of April 3, 1979 (44 FR 19894), FDA published a proposed rule classifying all known obstetrical and gynecological preamendments devices, including condoms. The proposed rule described the methods used by the agency to identify such preamendments devices, e.g., FDA's 1972 survey of device manufacturers, FDA's searches of published literature, and the activities of the Panel. Subsequently, in the

Federal Register of February 26, 1980 (45 FR 12710), FDA published a final rule classifying certain obstetrical and gynecological preamendments devices, including classifying the condom into class II (§ 884.5300 (21 CFR 884.5300)). The condom encompasses preamendments barrier-type sheaths that cover the entire shaft of the penis for purposes of contraception (preventing pregnancy), prophylaxis (preventing transmission of sexually transmitted diseases (STD's)), or semen collection (diagnostic testing). Preamendments devices characteristically falling within this classification are generally referred to as condoms.

Following classification of the condom into class II, FDA received two 510(k) notifications for ''female condoms'' intended to be inserted into the vagina and held in place to line the vaginal walls for purposes of contraception and prophylaxis. These 510(k) notifications claimed substantial equivalency to the condom identified in § 884.5300. Initially, in late 1987, in response to a 510(k) notification submitted by the Energy Basin Clinic to market a ''barrier female condom,'' FDA concurred that this condom, later called the Bikini Condom, was substantially equivalent to the class II condom (Ref. 1). Subsequently, in 1989, the agency received a 510(k) notification from the Wisconsin Pharmacal Co. for the WPC–333 female use condom-like device (WPC–333 device), later called the Femshield/Reality (Intra-) Vaginal Pouch and Reality Female Condom. This 510(k) submission brought new information to the agency's attention concerning the existence of a preamendments female use condom-like device.

The Wisconsin Pharmacal Co. claimed in its 510(k) notification that its WPC–333 device was substantially equivalent to the condom identified in § 884.5300 as well as to another preamendments device known as the Gee Bee Ring. Documentation in the 510(k) notification indicated that the Gee Bee Ring was a double-ringed pouch-type preamendments device intended for insertion into the vagina to line the walls of the vagina for contraceptive (pregnancy prevention) and prophylactic (prevention of STD's transmission) purposes (Ref. 2).

Upon receiving this information, FDA verified the existence, commercial distribution, and uses of the Gee Bee Ring, as best it could, through an affidavit and review of a May 1934 booklet printed contemporaneously with the distribution of the product (Refs. 2 and 3). The booklet entitled *A New Method for the Profession*, states on page 12, ''[T]he technique with this method (the modified Gee Bee technique) has a factor of safety equal to, if not better than, the diaphragm. It overcomes all the objections to the rubber condom * * *.'' These statements are taken by the agency to mean that the device was indicated as a contraceptive product (by reference to the diaphragm), and as a prophylactic product (by reference to the condom, which at that time (1934) was solely indicated as a prophylactic, i.e., for preventing the transmission of sexually related diseases). Subsequently, the agency presented this Gee Bee Ring information to the Panel as new information about a preamendments device not previously known to the agency.

During an open meeting held on March 7, 1989, (Ref. 14) the Panel reviewed all available information concerning the classification of a barrier-type pouch device that is inserted into the vagina prior to coitus and lines the vaginal wall and external cervix. Such available information indicated that the preamendments device, known as the Gee Bee Ring, was distributed, beginning in the 1930's and for some years thereafter, as a female condom, i.e., as a ''modified condom placed in the hands of the female * * * for proper insertion and use.'' (See Ref. 2.) The Panel determined that this particular device represented a generic type of preamendments device that the Panel identified as the vaginal pouch, rather than the condom, noting that the classification regulation for the condom device (§ 884.5300) identifies the condom as ''a sheath *which completely covers the penis* with a *closely fitting membrane*'' (emphasis added). The regulation also states that the condom is used ''for contraceptive and for prophylactic purposes (preventing transmission of sexually transmitted disease)'' and ''to collect semen to aid in the diagnosis of infertility.'' Because an intravaginal pouch loosely lines the interior of the vagina, rather than closely fitting the penis, and because there is no data to establish the safe and effective use of the intravaginal pouch, the Panel recommended that FDA not include the intravaginal pouch in the condom classification (§ 884.5300), but classify this generic type of device as a device that is distinct from condoms.

Subsequently, in April 1989, in response to the Wisconsin Pharmacal Co. 510(k), FDA advised the firm that its WPC–333 device is not substantially equivalent to either the condom identified in § 884.5300 or the Gee Bee Ring, due to design differences. As a result, in accordance with section 513(f) of the act, the device was automatically classified into class III (Ref. 4). In April 1989, FDA also advised the Energy Basin Clinic that the agency's response to the firm's 510(k) was incorrect, in that the firm's ''barrier female condom'' is not substantially equivalent to the condom as defined in § 884.5300 and that commercial marketing would misbrand the device under section 502(f) and (o) of the act (21 U.S.C. 352(f) and (o)) (Ref. 5).

During an August 25, 1989, open Panel meeting, FDA, the Panel, other Federal health agency experts, and interested parties discussed premarket testing requirements for female barrier contraceptives that also claim prevention of STD's transmission. Currently, postamendments female condoms are classified automatically by statute (section 513(f) of the act) into class III and in the **Federal Register** of June 7, 1990 (55 FR 23299), FDA has made available draft guidance describing the studies needed to support a PMA application for female condoms that also claim to prevent STD's (Ref. 6). This draft guidance describes the preclinical, clinical feasibility, and clinical safety and effectiveness studies needed to expedite the study and evaluation of PMA's for female condom devices that also claim prevention of STD's transmission. See the **ADDRESSES** section of this document for the guidance's availability.

On August 29, 1990, FDA responded to another 510(k) notification for a ''female condom'' which was submitted by MD Personal Products, Inc. (hereinafter referred to as MD Products). In response to the 510(k), FDA advised MD Products that its pouch-type device intended to line the vagina is not substantially equivalent to either the condom identified in § 884.5300 or the Gee Bee Ring, due to differences in technological characteristics and design (Ref. 7).

On May 29, 1993, FDA approved the PMA for the Wisconsin Pharmacal Co. ''Reality'' Female Condom (Ref. 8).

II. Recommendations of the Panel

During a public meeting held on March 7, 1989, the Panel made the following recommendations with respect to the classification of the intravaginal pouch:

A. Identification

The Panel recommended that the device be identified as follows: An intravaginal pouch is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for

contraceptive and prophylactic (preventing the transmission of STD's) purposes.

The Panel cautioned against the use of the term condom in the generic type of device because a condom is defined as ''a sheath which completely covers the penis with a closely fitting membrane,'' and use of the term to identify this generic type of device may be misunderstood by some persons to suggest that products in this group have the same performance characteristics as traditional full-sheath male condoms.

B. Recommended Classification of the Panel

The Panel recommended that the intravaginal pouch be classified into class III (premarket approval). The Panel unanimously recommended assigning a high priority to premarket approval because of the absence of testing and clinical medical data regarding the safety and effectiveness of the device and because device failure could result in release of semen into the vagina leading to unwanted pregnancies and transmission of disease, such as acquired immune deficiency syndrome (AIDS) caused by the human immunodeficiency virus (HIV) from HIV-infected semen. For women for whom pregnancy is contraindicated due to medical conditions such as heart disease or diabetes mellitus, the risk of an unwanted pregnancy can be severe, even life threatening.

C. Summary of Reasons for Recommendation

After reviewing the information provided by FDA, and after consideration of the open discussions during the Panel meeting and the Panel members' personal knowledge of and clinical experience with the device system, the Panel gave the following reasons in support of its recommendation to classify the intravaginal pouch into class III.

The Panel recommended that the intravaginal pouch be classified into class III because no published laboratory or clinical study data could be found that demonstrate the safety and effectiveness of the device. Reference to this type of device in past literature is limited (Ref. 2). More recent literature affirms the preliminary nature of certain studies; the need for in vitro and in vivo preclinical studies, including permeability studies of the device materials with respect to bacterial and viral STD-causing organisms; and the need for microbiological and clinical data that demonstrate the safety and contraceptive and prophylactic efficacy of this generic type of device (Ref. 9).

The Panel believed that the intravaginal pouch should be classified into class III because general controls and special controls would not provide reasonable assurance of the safety and effectiveness of the device, and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Although the safety of some device characteristics, such as the biocompatibility of device substances contacting the body, could be controlled through materials tests and specifications, the Panel believes there is insufficient evidence that a performance standard could be established to provide reasonable assurance of the safe and effective performance of the device. For example, no valid scientific evidence demonstrates whether, how often, or to what degree, the intravaginal pouch dislodges or becomes displaced during intercourse.

D. Summary of Data on Which the Recommendation is Based

The Panel based its recommendation on information provided by FDA, data and information contained in references 2 and 9, and on the Panel members' personal knowledge of, and experience with, contraceptive methods of birth control, including barrier-type contraceptives. Additionally, the Panel found no data in the literature or in studies discussed before the Panel to support the safety and effectiveness of the devices.

The Panel noted that failure of intravaginal pouches because of breakage, leakage, dislodgement, or displacement that leads to the release of semen, could result not only in undesired pregnancies, but also in the transmission of STD's, such as AIDS. Therefore, the Panel recommended that the labeling of these devices contain use effectiveness information, particularly, pregnancy rate information, and adequate indications and directions for use. The Panel believed that the device must be subject to premarket approval to assure that manufacturers demonstrate the satisfactory performance of the device for its intended use or uses, thereby providing reasonable assurance of its safety and effectiveness.

E. Risks to Health

The Panel identified the following risks to health associated with use of the device:

1. Pregnancy

Leakage, breakage, dislodgement, or displacement of the device during sexual intercourse could result in the occurrence of an undesired pregnancy.

2. Disease Transmission

If the device fails due to leakage, breakage, dislodgement, or displacement, contact with infected semen or vaginal secretions or mucosa could result in the transmission of STD's, including HIV (causing AIDS).

3. Adverse Tissue Reaction

Unless the biocompatibility of materials and substances comprising the device are tested, local tissue irritation, and sensitization or systemic toxicity could occur when the vaginal pouch contacts the vaginal wall and cervical mucosa, and the penis.

4. Ulceration and Other Physical Trauma

III. Proposed Classification

On its own initiative, FDA is proposing to change the name of the generic type of device identified by the Panel from ''intravaginal pouch'' to ''female condom.'' FDA agrees with the Panel's finding that the female condom represents a type of preamendments device that has different technological characteristics than the preamendments condom identified in § 884.5300 and concurs with the Panel's recommendation that the female condom not be considered a type of device that falls within the classification category of condom (§ 884.5300).

FDA believes that the proposed name, ''female condom,'' better connotes the intended female use and purposes of the device than does the term, ''intravaginal pouch,'' i.e., female usage of the pouch-like device to line the vaginal walls for purposes of preventing pregnancy and STD's transmission. Adequate labeling for female condoms, including adequate directions for use, and actual usage by female users will make clear to sexual partners the differences between female condoms and male condoms.

FDA disagrees with the Panel's concern that the use of the term ''condom'' to describe or make reference to the female condom may imply that the female condom will have the same contraceptive and prophylactic effectiveness as a condom, as defined in § 884.5300, in preventing undesired pregnancy and protecting against STD's, including AIDS. The agency believes any such misconception can be dispelled by requiring that the labeling of the female condom device clearly and adequately state the contraceptive failure rates pertinent to any claims made for preventing undesired pregnancy and adequately describe clinical effectiveness data, including

pertinent information on the impermeability of the device to sexually transmitted viral or bacterial disease, associated with any prophylactic claims for protection against STD's, including AIDS.

FDA notes that differences in technological characteristics and design among devices within the same generic type of device may raise new questions of safety and effectiveness that prevent the devices from being substantially equivalent to one another. Such was the case for the 510(k) notifications for certain postamendments female condoms claiming substantial equivalence to the preamendments female condom, the Gee Bee Ring. In the preamble of the final rule setting forth classification procedures (43 FR 32988 at 32989, July 28, 1978), FDA noted that ''The term 'generic type of device' describes FDA's grouping, for reasons of administrative convenience, of devices that are to be regulated in the same way because they present *similar safety and effectiveness concerns*. A generic type of device will include devices that may or *may not be* 'within a type' and 'substantially equivalent' to each other.'' (Emphasis added.)

FDA believes the female condom should be classified into class III because general controls and special controls would not provide reasonable assurance of the safety and effectiveness of the device and the device is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. FDA believes that the calling for PMA's for this device should be a high priority.

FDA agrees with the Panel's conclusions and recommendations regarding the unproven contraceptive effectiveness of the preamendments female condom and its indeterminate efficacy in protecting against the transmission of STD's. The agency has neither received nor found in the literature valid scientific evidence from laboratory tests, preclinical studies, or clinical investigations that does the following: (1) Demonstrates the biocompatibility of materials used in the preamendments female condom; (2) measures performance characteristics, such as displacement, dislodgement, bursting, and tearing; (3) assesses the contraceptive safety and effectiveness of the preamendments device in preventing pregnancy, in terms of reported failure or pregnancy rates based upon usage (Refs. 2, 9, and 10); or (4) demonstrates the prophylactic efficacy of the preamendments device in protecting against the transmission of STD's, including HIV (Refs. 10 through 13). The agency believes that the present voluntary industry standard and the agency's methodology for testing conventional condoms for pinhole leaks are not suitable for testing the female condom for leaks without significant modification and validation.

FDA notes that the labeling of certain marketed barrier contraceptive devices, such as the contraceptive diaphragm and accessories (21 CFR 884.5350), and the cervical cap (21 CFR 884.5250), identify pregnancy rates associated with the use of the devices. The expected failure or pregnancy rates for use of the conventional full-sheath condom are widely published. Such information is not available for the preamendments female condom device. Consequently, the agency agrees with the Panel that pregnancy rate information, derived from valid clinical study data, should be included in female condom labeling. Otherwise, the labels would fail to disclose a material fact regarding the consequences which may result from using the female condom.

IV. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

V. Environmental Impact

The agency has 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.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA believes that there is likely no interest at this time in marketing the device to be classified by this rule. FDA is taking this action because it has determined that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device, if there is any interest in marketing one in the future. Without this rule (and a subsequent requirement for PMA's), a person could market a device by claiming substantial equivalence to the Gee Bee Ring. All premarket submissions for ''female condom'' type devices that FDA has received to date have been for devices that have been found to be not substantially equivalent to the Gee Bee Ring and, therefore, those devices are not preamendments devices and are not to be classified by this rule. If a final rule is issued classifying these devices in class III, FDA would be required to undertake subsequent notice and comment rulemaking to establish an effective date by which PMA's would be required for this device. Under section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), a rule requiring PMA's for this device could not take effect any sooner than 30 months after the effective date of a final rule classifying the device or 90 days after publication of the final rule requiring the PMA's, whichever is later.

The agency therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule requires no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Submission of Comments

Interested persons may, on or before September 8, 1999, submit to the Dockets Management Branch (address above) 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.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter from the Office of Device Evaluation, CDRH, FDA, to the Energy Basin Clinic regarding substantially equivalent determination for the Barrier Condom, August 3, 1987.

2. Beadle, E. L., ''A New Method for the Profession: Outline of Successful Prophylactic Program,'' The Hemingway Press, Waterbury, CN, 1934.

3. Affidavit from Richard Beadle to FDA regarding the Gee Bee Ring, its labeling, and its distribution, July 17, 1989.

4. Letter from the Office of Device Evaluation, CDRH, FDA, to the Wisconsin Pharmacal Co. regarding the not substantially equivalent determination for the WPC–333 Vaginal or Female Condom, April 14, 1989.

5. Letter from the Office of Device Evaluation, CDRH, FDA, to the Energy Basin Clinic regarding the not substantially equivalent determination for the Barrier Condom, April 26, 1989.

6. CDRH, FDA guidance document entitled ''Premarket Testing Guidelines for Female Barrier Contraceptive Devices Also Intended to Prevent Sexually Transmitted Diseases,'' April 4, 1990.

7. Letter from the Office of Device Evaluation, CDRH, FDA, to MD Personal Products, Inc., regarding the not substantially equivalent determination for the Women's Choice Brand Condom,'' August 29, 1990.

8. Letter from the Office of Device Evaluation, CDRH, FDA, to the Wisconsin Pharmacal Co. regarding PMA approval for the ''Reality'' Female Condom, May 7, 1993.

9. Bounds, W., J. Guillebaud, L. Stewart, and S. Steele, ''A Female Condom (Femshield™); A Study of its User-Acceptability,'' *British Journal of Family Planning*, 14:83, 1988.

10. Bounds, W., ''Male and Female Condoms,'' *British Journal of Family Planning*, 15:14, 1989.

11. Connell, E. B., ''Barrier Contraceptives,'' *Clinical Obstetrics and Gynecology*, 32:377, 1989.

12. Harris, J. R., L. W. Kanagas, and J. D. Shelton, ''Role of Condoms in Preventing HIV Transmission in Developing Countries,'' *Heterosexual Transmission of AIDS*, ch. 32, p. 399, Alan R. Liss, Inc., 1990.

13. Gregersen, E., and B. Gregersen, ''The Female Condom—A Pilot Study of the Acceptability of a New Female Barrier Method,'' *Acta Obstetricia ET Gynecologica Scan*, 69:73, 1990.

14. Obstetrics-Gynecology Devices Panel, transcript and meeting minutes, March 7, 1989.

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, it is proposed that 21 CFR part 884 be amended as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 884.5330 is added to subpart F to read as follows:

§ 884.5330 Female condom.

(a) *Identification*. A female condom is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. It is indicated for contraceptive and prophylactic (preventing the transmission of sexually transmitted diseases) purposes.

(b) *Classification*. Class III (premarket approval).

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required*. No effective date has been established of the requirement for premarket approval for the devices described in paragraph (b) of this section. See § 884.3 for effective dates of requirement for premarket approval.

Dated: May 28, 1999.

Linda S. Kahan,

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

[FR Doc. 99–14653 Filed 6–9–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI72–01–7280; FRL–6357–2]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to disapprove a revision to Michigan's State Implementation Plan (SIP) which would change the State's definition of volatile organic compound (VOC). The Michigan Department of Environmental Quality (MDEQ) submitted this revision on August 20, 1998 and supplemented it with a November 3, 1998, letter.

DATES: Comments on this proposed action must be received by July 12, 1999.

ADDRESSES: You may send written comments to: Carlton T. Nash, Chief, Regulation Development Section, Air Programs Branch (AR–18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the proposed SIP revision and EPA's analysis are available for inspection at the following location: United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Kathleen D'Agostino at (312)886–1767 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Kathleen D'Agostino, Environmental Engineer, Regulation Development Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–1767.

SUPPLEMENTARY INFORMATION:

A. Background Information
B. Contents of State Submittal and EPA's Evaluation
C. EPA's Proposed Action

A. Background

On August 20, 1998, the MDEQ submitted to EPA a proposed revision to the Michigan SIP. MDEQ supplemented the proposed revision with a November 3, 1998, letter from Robert Irvine. The submittal included a revision to the State's definition of VOC, as well as other rule revisions and rescissions. In this document EPA is proposing action only on the revision to the definition of VOC, R 336.1122(f). We will address the remaining rule revisions and rescissions in separate rulemaking actions.

B. Contents of State Submittal and EPA's Evaluation

The State's definition of the term ''volatile organic compound'' is ''any compound of carbon, or mixture of compounds of carbon that participates in photochemical reactions, excluding the following materials, all of which do not contribute appreciably to the formation of ozone: * * * *'' The definition goes on to list the exempt compounds. The wording of the State definition is ambiguous, in that it could