SUPPLEMENTARY INFORMATION: On May 25, 1999, the Commission received a Petition for Rulemaking from Mary Clare Wohlford, William T. Wohlford and Martin T. Mortimer regarding the Commission's candidate debate regulations at 11 CFR 110.13. Paragraph (c) of that section states, *inter alia,* that ''[f]or all debates, staging organization(s) must use pre-established objective criteria to determine which candidates may participate in a debate.'' *Id*. The petitioners assert that the objective criteria for inclusion in Presidential and Vice Presidential debates should be established by the Commission itself, and not left to the discretion of debate staging organizations. Therefore, the petition urges the Commission to revise this paragraph to set forth ''mandatory criteria for participation in Presidential and Vice Presidential Debates.'' Petition at 1.

Specifically, the petition recommends that the debates be open to any candidate that (1) has the mathematical potential to win the election in that he or she is on the ballot in enough states to earn 270 Electoral College votes; and (2) has proven his or her viability by having spent at least $500,000 on the campaign by the end of the month preceding the date of the first scheduled debate held on or after September 1 of the election year. In addition, the petition recommends that candidates have equal access to debates held before September 1 without regard to the above requirements.

Copies of the petitions are available for public inspection in the Commission's Public Records Office, 999 E Street, NW., Washington, DC 20463, Monday through Friday between the hours of 9:00 a.m. and 5:00 p.m. Copies of the petitions can also be obtained at any time of the day and week from the Commission's home page at www.fec.gov, or from the Commission's FlashFAX service. To obtain copies of the petitions from FlashFAX, dial (202) 501–3413 and follow the FlashFAX service instructions. Request document # 239 to receive the petition.

All statements in support of or in opposition to the petitions should be addressed to Rosemary C. Smith, Senior Attorney, and must be submitted in either written or electronic form. Written comments should be sent to the Commission's postal service address: Federal Election Commission, 999 E Street, NW., Washington, DC 20463. Faxed comments should be sent to (202) 219–3923. Commenters submitting faxed comments should also submit a printed copy to the Commission's postal service address to ensure legibility. Comments may also be sent by electronic mail to debates@fec.gov. Commenters sending comments by electronic mail should include their full name, electronic mail address and postal service address within the text of their comments. All comments, regardless of form, must be submitted by July 12, 1999.

Consideration of the merits of the petition will be deferred until the close of the comment period. If the Commission decides that the petition has merit, it may begin a rulemaking proceeding. Any subsequent action taken by the Commission will be announced in the **Federal Register**.

Dated: June 4, 1999.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 99–14714 Filed 6–9–99; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 24

[Docket No. 99–09]

RIN 1557-AB69

Community Development Corporations, Community Development Projects, and Other Public Welfare Investments

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of the Comptroller of the Currency (OCC) is proposing to amend part 24, the regulation governing national bank investments that are designed primarily to promote the public welfare. This proposal simplifies the prior notice and self-certification requirements that apply to national banks' public welfare investments; expands the types of investments that a national bank may self-certify by removing geographic restrictions; and permits eligible national banks with assets of less than $250 million to self-certify any public welfare investment. The OCC is also seeking comment on whether to modify the methods of demonstrating community support or participation currently prescribed by part 24, and whether the OCC could simplify or streamline the procedures and standards contained in part 24. The proposal encourages national banks to make public welfare investments by making it easier to comply with the applicable procedures.

DATES: Comments must be received on or before August 9, 1999.

ADDRESSES: Please direct comments to: Docket No. 99–09, Communications Division, Third Floor, Office of the Comptroller of the Currency, 250 E Street, SW, Washington, DC, 20219. Comments are available for inspection and photocopying at that address. In addition, comments may be sent by facsimile transmission to FAX number (202) 874-5274, or by electronic mail to REGS.COMMENTS@OCC.TREAS.GOV.

FOR FURTHER INFORMATION CONTACT: David Lewis, Community Development Investments Manager, Community Development Division, (202) 874–4930; Michael S. Bylsma, Director, Community and Consumer Law Division, (202) 874–5750; or Heidi M. Thomas, Senior Attorney, Legislative and Regulatory Activities Division, (202) 874–5090.

SUPPLEMENTARY INFORMATION:

Background

The OCC is proposing to amend 12 CFR part 24, which contains the rules relating to national banks' investments in community development corporations (CDCs), community development (CD) projects, and other public welfare investments. Part 24 implements 12 U.S.C. 24(Eleventh), which authorizes national banks to make investments designed primarily to promote the public welfare, including the welfare of low- and moderate-income communities and families, subject to certain percentage of capital limitations. (The investments authorized pursuant to 12 U.S.C. 24(Eleventh) are collectively referred to in this proposal as ''public welfare investments''). The purpose of this proposal is to make burden-reducing changes that will make it easier for national banks to use the public welfare investment authority that the statute and regulation provide.

The OCC originally adopted part 24 in 1993 and substantially revised the regulation, pursuant to its Regulation Review Program, in 1996. *See* 58 FR 68464 (Dec. 27, 1993) (final regulation); 61 FR 49654 (Sept. 23, 1996) (1996 amendments). The 1996 amendments encouraged national banks to make public welfare investments by eliminating unnecessarily burdensome provisions and streamlining the part 24 procedures. Among other things, the 1996 amendments: modified the test for determining whether an investment primarily promotes the public welfare; streamlined the investment self-certification and prior approval

procedures; and expanded the list of activities eligible for self-certification.

The OCC is committed to continually reevaluating its rules to reduce unnecessary regulatory burden and simplify compliance, consistent with the safe and sound operation of national banks. This proposal addresses several issues regarding national bank compliance with part 24 that have arisen since 1996. Specifically, the proposal further simplifies the prior notice and self-certification requirements that apply to national banks' public welfare investments; further expands the types of investments a national bank may self-certify by removing geographic restrictions; and permits an eligible community bank to self-certify any public welfare investment. An eligible community bank is an eligible bank [1] with assets of less than $250 million.

Description of the Proposal

Community Benefit Information Requirement (§ 24.3(c))

Current § 24.6 lists certain public welfare investments that an eligible bank may make by submitting a self-certification letter to the OCC within 10 working days after it makes the investment. No prior notification or approval is required. For all other public welfare investments, a national bank must submit an investment proposal to the OCC for prior approval. Unless otherwise notified in writing by the OCC, the proposed investment is deemed approved 30 calendar days from the date on which the OCC receives the bank's investment proposal.

Regardless of which procedure applies, § 24.3(c) currently requires a national bank making a public welfare investment to demonstrate the extent to which the investment benefits communities otherwise served by the bank. (The requirement of § 24.3(c) is referred to in this proposal as the community benefit information requirement.) Section 24.5 requires the bank to provide a statement in its self-certification letter or investment proposal certifying that it has complied with this requirement.

The OCC is proposing to remove the community benefit information requirement, because this requirement is not mandated by statute and may constrict national banks from making otherwise qualifying and beneficial public welfare investments. Moreover, the OCC's experience in implementing 12 CFR part 24 suggests that national banks are seeking more public welfare investment opportunities across broader geographic markets than previously. Enhanced interstate operations and the increasing availability of Internet banking and other forms of remote banking limit the value of the community benefit information requirement for the OCC's evaluation of investment proposals.

Although, as a matter of law, a bank's authority to make public welfare investments pursuant to 12 U.S.C. 24(Eleventh) and 12 CFR part 24 is independent of its obligation to serve the credit needs of its entire community under the Community Reinvestment Act (CRA), the OCC recognizes that banks may want the OCC to consider a public welfare investment for CRA purposes. Retention of the community benefit information requirement is not necessary, however, to facilitate the identification of a public welfare investment that a bank believes should be considered for CRA purposes. Instead, the OCC proposes to amend § 24.5 to provide that a national bank that wants the OCC to consider a specific public welfare investment during a CRA examination may include a simple statement to that effect in its public welfare investment proposal or self-certification letter.[2]

Demonstration of Community Support (§ 24.3(d))

Under section 24.3(d), a national bank may make investments pursuant to part 24 if it demonstrates that it has non-bank community support for, or participation in, the investment. Section 24.3(d) provides that a national bank may demonstrate this support or participation in a number of ways, including:

(1) In the case of an investment in a CD entity with a board of directors, representation on the board of directors by non-bank community representatives with expertise relevant to the proposed investment;

(2) Establishment of an advisory board for the bank's community development activities that includes non-bank community representatives with expertise relevant to the proposed investment;

(3) Formation of a formal business relationship with a community-based organization in connection with the proposed investment;

(4) Contractual agreements with community partners to provide services in connection with the proposed investment;

(5) Joint ventures with local small businesses in the proposed investment; and

(6) Financing for the proposed investment from the public sector or community development organizations.

Prior to the 1996 amendments, part 24 required the affected primary beneficiaries and representatives of local or State government to have endorsed and demonstrated support for the investment. In the case of a CDC, a bank had to demonstrate support through non-bank community participation on the organization's board of directors. 12 CFR 24.4(a)(3) (1993). The OCC modified the community support/participation requirement in the 1996 amendments to provide banks and community groups more flexibility in structuring community partnerships under part 24. The OCC added the nonexclusive list of examples of community support or participation to the final rule in response to comments on the 1996 proposal.

The OCC has not changed § 24.3(d) in this proposal, but invites comment on whether the approach adopted in the 1996 amendments is effective in encouraging community involvement in national banks' public welfare investments. For example, is the current non-bank community support or participation requirement appropriate? Are there other ways of demonstrating support or participations? In particular, commenters addressing these issues are invited to discuss whether:

(1) The current community participation prong of the public welfare test has been sufficient in obtaining evidence of adequate community support and involvement in national banks' community development investments;

(2) General letters of support from community groups or local officials, without other evidence of community support or participation, should be considered sufficient to satisfy this requirement;

(3) Stricter requirements for community support or participation will have the effect of discouraging public welfare investments pursuant to part 24; and

(4) Institutions should demonstrate community support for, or participation in, investments in national or regional

[1] Part 24 defines an ''eligible bank'' as a national bank that is well capitalized, has a composite rating of 1 or 2 under the Uniform Financial Institutions Rating System (the CAMELS rating), has a Community Reinvestment Act rating of ''Outstanding'' or ''Satisfactory,'' and is not subject to a cease and desist order, consent order, formal written agreement, or Prompt Corrective Action directive. 12 CFR 24.2(e).

[2] The OCC's approval of a public welfare investment made pursuant to 12 CFR part 24 does not affect how the investment is evaluated for CRA purposes, and an investment approved under part 24 is not necessarily a qualified investment for purposes of CRA.

community development investment vehicles, and if so, what form this demonstration should take.

Self-Certification of Public Welfare Investments by an Eligible Community Bank (§ 24.5(a))

An eligible national bank may make public welfare investments listed in § 24.6 without prior OCC approval by submitting a self-certification letter to the OCC that satisfies the requirements in the regulation. 12 CFR 24.5(a). Investments eligible for self-certification include certain investments relating to low- and moderate-income housing, small businesses located in low- and moderate-income areas, employment or job training for low- or moderate-income individuals, or technical assistance services for non-profit community development organizations; investments as a limited partner in certain low-income housing tax credit projects; investments in national banks with a community development focus; investments approved by the Federal Reserve Board under 12 CFR 208.21; and investments previously determined by the OCC to be permissible under part 24. 12 CFR 24.6. Other investments require application to, and approval by, the OCC.

Because community banks operate with more limited resources than larger institutions, the tasks associated with the prior approval process for public welfare investments place a greater burden on them. In addition, the OCC recognizes that smaller community banks may serve as the only source of investments for some CDCs and CD projects located in small towns or rural areas and that the prior approval process may inhibit community banks from making these investments. The proposal therefore amends § 24.5(a) to permit eligible community banks (national banks with less than $250 million in assets) to self-certify *all* public welfare investments, not only those investments listed in § 24.6. This change will reduce the regulatory burden and costs associated with the part 24 prior approval process for eligible community banks in particular and may encourage more community banks to make public welfare investments in local CDCs and CD projects that might not be able to attract investments from other sources.

This change is consistent with 12 U.S.C. 24 (Eleventh), which does not require a national bank to receive prior OCC approval before making a public welfare investment within the 5 percent of capital aggregate limit. Moreover, the change does not raise safety and soundness concerns because the application process is eliminated only for investments by eligible community banks. The eligibility standard in § 24.2(e) ensures that only well-capitalized, well-run community banks can take advantage of this streamlined approach. In addition, these public welfare investments are subject to review during the examination process pursuant to § 24.7. Finally, as set forth in § 24.7, if the OCC finds that an investment violates law or regulation, is inconsistent with the safe and sound operation of the bank, or poses a significant risk to the deposit insurance fund, it may require the bank to take appropriate remedial action.

The Local Community Investment Requirement for Self-Certification (§ 24.6(b)(2))

Currently, part 24 does not permit a national bank to self-certify an investment if, among other things, more than 25 percent of the investment is used to fund projects that are located in a State or metropolitan area other than the States or metropolitan areas in which the bank maintains its main office or has branches. 12 CFR 24.6(b)(2). If any portion of a bank's investment funds projects outside of its local areas, the bank must include in its self-certification letter a statement that no more than 25 percent of the investment funds these projects. 12 CFR 24.5(a)(3)(vii).

The OCC proposes to remove this local community investment requirement in § 24.6(b) so that a national bank can use the less burdensome self-certification process to make eligible public welfare investments in *any* area. This change removes a requirement that is not necessary to implement the statute because, as discussed in connection with the removal of the community benefit information requirement, 12 U.S.C. 24 (Eleventh) does not require that a bank link its public welfare investments to the communities it serves. In addition, this change permits national banks to use the self-certification process for investments in national community development investment vehicles. Because these vehicles often provide funds for projects located throughout the United States, it has not always been possible for a bank to certify that not more than 25 percent of the bank's investment will support projects in States or metropolitan areas other than those in which the bank's main office or branches are located. Thus, this change should expand the opportunities for banks to fund worthwhile public welfare projects.

As with the proposal to remove the community benefit information requirement, the OCC recognizes that, in some cases, the local community investment requirement for self-certification has served as a way for banks to identify investments that they believe may be eligible for CRA credit. For the same reasons as discussed in connection with that change, a bank that wants the investment to be considered for CRA purposes may include a statement to that effect in its self-certification letter. This information will be provided to supervisory staff in connection with the bank's CRA examination. The OCC notes that this change affects only the eligibility of the investment for self-certification. It does not modify either the part 24 standards for permissible public welfare investments or the CRA standards set forth in 12 CFR Part 25.

Comments

The OCC requests comment on all aspects of this proposal, including the extent to which these proposed changes will encourage national banks to make public welfare investments. Commenters are also invited to suggest other revisions that would simplify the standards or streamline the procedures currently contained in part 24.

In addition, the OCC seeks comment on the impact of this proposal on community banks. As discussed in connection with certain of the proposed changes, the OCC recognizes that community banks operate with more limited resources than larger institutions and may present a different risk profile. Thus, the OCC specifically requests comment on the impact of the proposal on community banks' current resources and available personnel with the requisite expertise, and whether the goals of the proposal could be achieved, for community banks, through an alternative approach.

Finally, the OCC solicits comment on whether the proposal is written clearly and is easy to understand. On June 1, 1998, the President issued a Memorandum directing each agency in the Executive branch to write its rules in plain language. This directive applies to all new proposed and final rulemaking documents issued on or after January 1, 1999. The OCC invites comment on how to make this proposal clearer. For example, you may wish to discuss:

(1) Whether we have organized the material to suit your needs;

(2) Whether the requirements of the rule are clear; or

(3) Whether there is something else we could do to make the rule easier to understand.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, the Comptroller of the Currency certifies that this proposal would not have a significant economic impact on a substantial number of small entities in accord with the spirit and purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Accordingly, a regulatory flexibility analysis is not required. The proposal would reduce regulatory burden on national banks by simplifying the prior approval process and simplifying and expanding the self-certification process for part 24 investments. The economic impact of this proposal on national banks, regardless of size, is expected to be minimal.

Paperwork Reduction Act

For purposes of compliance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*, the OCC invites comment on:

(1) Whether the proposed collections of information contained in this notice of proposed rulemaking are necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(2) The accuracy of the OCC's estimate of the burden of the proposed information collection;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected;

(4) Ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology; and

(5) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Recordkeepers are not required to respond to this collection of information unless it displays a currently valid OMB control number.

The collection of information requirements contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Paperwork Reduction Project 1557–0194, Washington, D.C. 20503, with copies to Office of the Comptroller of the Currency, Communications Division, 250 E Street, SW, Attention: Paperwork Reduction Project 1557–0194, Washington, D.C. 20219.

The proposal is expected to reduce annual paperwork burden for recordkeepers because it eliminates certain application and self-certification requirements. The collection of information requirements in this proposal are found in 12 CFR 24.5. This information is required for the public welfare investment self-certification and prior approval procedures. The likely respondents are national banks.

Estimated average annual burden hours per recordkeeper: 1.9. Start-up costs: None.

Executive Order 12866 Determination

The Comptroller of the Currency has determined that this proposal does not constitute a ''significant regulatory action'' for the purposes of Executive Order 12866.

Unfunded Mandates Reform Act of 1995 Determinations

Section 202 of the Unfunded Mandates Reform Act of 1995, Pub. L. 104–4 (Unfunded Mandates Act) requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. If a budgetary impact statement is required, Section 205 of the Unfunded Mandates Act also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. As discussed in the preamble, this proposed rule is limited to the prior notice and self-certification process for part 24 investments. The OCC therefore has determined that the proposal will not result in expenditures by State, local, or tribal governments or by the private sector of $100 million or more. Accordingly, the OCC has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

List of Subjects in 12 CFR Part 24

Community development, Credit, Investments, National banks, Reporting and recordkeeping requirements.

Authority and Issuance

For the reasons set forth in the preamble, the OCC proposes to amend part 24 of chapter I of title 12 of the Code of Federal Regulations to read as follows:

PART 24—COMMUNITY DEVELOPMENT CORPORATIONS, COMMUNITY DEVELOPMENT PROJECTS, AND OTHER PUBLIC WELFARE INVESTMENTS

1. The authority citation for part 24 continues to read as follows:

Authority: 12 U.S.C. 24 (Eleventh), 93a, 481 and 1818.

2. In § 24.2, paragraphs (f), (g), (h) and (i) are redesignated as paragraphs (g), (h), (i) and (j), and a new paragraph (f) is added to read as follows:

§ 24.2 Definitions.

* * * * *

(f) *Eligible community bank* means an eligible bank that, as of December 31 of either of the prior two calendar years had total assets of less than $250 million.

* * * * *

§ 24.3 [Amended]

3. In § 24.3, paragraph (c) is removed, and paragraph (d) is redesignated as paragraph (c).

4. In § 24.5, paragraph (a)(1) and paragraph (a)(3)(iii) are revised, paragraph (a)(3)(v) is amended by adding the word ''and'' at the end of the paragraph, paragraph (a)(3)(vi) is amended by removing the term ''; and'' and adding a period in its place at the end of the sentence, paragraph (a)(3)(vii) is removed, paragraph (a)(4) is redesignated as paragraph (a)(5), a new paragraph (a)(4) is added, paragraph (b) is amended by redesignating paragraph (b)(3) through (b)(6) as paragraphs (b)(4) through (b)(7), and a new paragraph (b)(3) is added to read as follows:

§ 24.5 Public welfare investment self-certification and prior approval procedures.

(a) * * *

(1) Subject to § 24.4(a), an eligible bank may make an investment described in § 24.6(a) and an eligible community bank may make any investment that satisfies the requirements of § 24.3 without prior notification to, or approval by, the OCC if the bank follows the self-certification procedures in this section.

* * * * *

(3) * * *

(iii) The type of investment (equity or debt), the investment activity listed in § 24.3(a) or § 24.6(a), as applicable, that the investment supports, and a brief description of the particular investment;

* * * * *

(4) If the bank wants the OCC to consider the investment during an examination under the CRA (12 U.S.C. 2901 *et seq.*) 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 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