§ 600.1015 Late charges.

The late charge to fish buyers for fee payment, collection, deposit, and/or disbursement shall be one and one-half (1.5) percent per month, or the maximum rate permitted by state law, for the total amount of the fee not paid, collected, deposited, and/or disbursed when due to be paid, collected, deposited, and/or disbursed. The full late charge shall apply to the fee for each month or portion of a month that the fee remains unpaid, uncollected, undeposited, and/or undisbursed.

§ 600.1016 Enforcement.

In accordance with applicable law or other authority, NMFS may take appropriate action against each fish seller and/or fish buyer responsible for non-payment, non-collection, non-deposit, and/or non-disbursement of the fee in accordance with this subpart to enforce the collection from such fish seller and/or fish buyer of any fee (including penalties and all costs of collection) due and owing the United States on account of the loan that such fish seller and/or fish buyer should have, but did not, pay, collect, deposit, and/or disburse in accordance with this subpart. All such loan recoveries shall be applied to reduce the unpaid balance of the loan.

§ 600.1017 Prohibitions and penalties.

(a) The following activities are prohibited, and it is unlawful for any party to: (1) Vote in any referendum under this subpart if the party is ineligible to do so;

(2) Vote more than once in any referendum under this subpart;

(3) Sign or otherwise cast a ballot on behalf of a voter in any referendum under this subpart unless the voter has fully authorized the party to do so and doing so otherwise comports with this subpart;

(4) Interfere with or attempt to hinder, delay, buy, or otherwise unduly or unlawfully influence any eligible voter's vote in any referendum under this subpart;

(5) Submit a fraudulent, unauthorized, incomplete, misleading, unenforceable by specific performance, or inaccurate bid in response to an invitation to bid under this subpart or, in any other way, interfere with or attempt to interfere with, hinder, or delay, any invitation to bid, any bid submitted under any invitation to bid, any reduction contract, or any other reduction process in connection with any invitation to bid;

(6) Revoke or attempt to revoke any bid under this subpart;

(7) Fail to comply with the terms and conditions of any invitation to bid, bid, or reduction contract under this subpart, including NMFS' right under such reduction contracts to specific performance;

(8) Fail to fully and properly pay and collect any fee due payable, and collectible under this subpart or otherwise avoid, decrease, interfere with, hinder, or delay any such payment and collection,

(9) Convert, or otherwise use for any purpose other than the purpose this subpart intends, any paid or collected fee;

(10) Fail to fully and properly deposit on time the full amount of all fee revenue collected under this subpart into a deposit account and disburse the full amount of all deposit principal to the Fund's lockbox account—all as this subpart requires;

(11) Fail to maintain full, timely, and proper fee payment, collection, deposit, and/or disbursement records or make full, timely, and proper reports of such information to NMFS—all as this subpart requires;

(12) Fail to advise NMFS of any fish seller's refusal to pay, or of any fish buyer's refusal to collect, any fee due and payable under this subpart;

(13) Refuse to allow NMFS or agents that NMFS designates to review and audit at reasonable times all books and records reasonably pertinent to fee payment, collection, deposit, disbursement, and accounting under this subpart or otherwise interfere with, hinder, or delay NMFS or it agents in the course of their activities under this subpart;

(14) Make false statements to NMFS, any of the NMFS' employees, or any of NMFS' agents about any of the matters in this subpart;

(15) Obstruct, prevent, or unreasonably delay or attempt to obstruct, prevent, or unreasonably delay any audit or investigation NMFS or its agents conduct, or attempt to conduct, in connection with any of the matters in this subpart; and/or

(16) Otherwise materially interfere with the efficient and effective conduct of reduction and the repayment of reduction loans under this subpart.

(b) Any party who violates one or more of the prohibitions of paragraph (a) of this section is subject to the full range of penalties the Magnuson-Stevens Act and 15 CFR part 904 provide—including, but not limited to: civil penalties, sanctions, forfeitures, and punishment for criminal offenses—and to the full penalties and punishments otherwise provided by any other applicable law of the United States.

(c) Additionally, NMFS may take any and all appropriate actions, including the communication of action at law, against each party responsible for the non-payment, non-collection, non-deposit, and/or non-disbursement in accordance with § 600.1013 and/or § 600.1014 to enforce the United States' receipt from such party of any fee—including penalties and all costs of collection—due and owing the United States on account of the reduction loan that such party should have, but did not, pay, collect, deposit, and/or disburse in accordance with § 600.1013 and/or § 600.1014. All such reduction loan recoveries shall be applied to reduce the unpaid balances of reduction loans.

§ 600.1018 Implementation regulations for each program. [Reserved]

[FR Doc. 00–12159 Filed 5–17–00; 8:45 am]

BILLING CODE 3510–22–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 99N–1309]

Obstetrical and Gynecological Devices; Classification of Female Condoms

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the preamendments female condom intended for contraceptive and prophylactic purposes. Under this rule, the preamendments female condom is being classified into class III (premarket approval). This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the FDA Modernization Act of 1997.

DATES: This rule is effective June 19, 2000.

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

In a proposal published in the **Federal Register** of June 10, 1999 (64 FR 31164)

(hereinafter referred to as the June 10, 1999, proposal), FDA solicited comments regarding the proposed classification of female condoms. The June 10, 1999, proposal provided the regulatory history of female condoms, as well as the recommendation of the Obstetrical and Gynecological Device Classification Panel (the Panel) that this particular device be classified into class III. Specifically, the Panel recommended that this device be classified into class III because no published laboratory or clinical study data could be found that demonstrate its safety and effectiveness. Also, the Panel believed that 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 agreed with the Panel's recommended classification.

The Panel also recommended that the device be identified as an intravaginal pouch because it is a sheath-like device that lines the vaginal wall and is inserted into the vagina prior to the initiation of coitus. FDA proposed to change the name of the generic type of the device to female condom.

The 90-day comment period ended September 8, 1999, and FDA stated that upon consideration of public comment it would issue a final rule classifying this device. FDA received one comment endorsing the June 10, 1999, proposal.

II. Conclusion

FDA has concluded that the female condom be classified into class III because general controls and special controls do 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 has further concluded that the generic type of this device be identified as ''female condom.'' FDA intends to issue a call for premarket approval applications (PMA's) for these devices.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the rule under Executive Order 12866, Executive Order 13132, the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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.

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

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 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. 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 rule will not have a significant economic impact on a substantial number of small entities. In addition, this 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.

V. Paperwork Reduction Act of 1995

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

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:

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 9, 2000.

Linda S. Kahan,

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

[FR Doc. 00–12526 Filed 5–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 701

Department of the Navy Privacy Act Program

AGENCY: Department of the Navy.

ACTION: Final rule.

SUMMARY: On September 14, 1999, at 64 FR 49850, the Department of the Navy unintentionally deleted subparts F and G to 32 CFR part 701. These subparts provide the policies and procedures for the Department of the Navy Privacy Program and are still current and relevant to the Navy's Privacy Program. Therefore, this final rule adds subparts F and G to 32 CFR part 701.

EFFECTIVE DATE: September 14, 1999.

FOR FURTHER INFORMATION CONTACT: Mrs. Doris Lama at (202) 685-6545.

SUPPLEMENTARY INFORMATION:

Executive Order 12866, 'Regulatory Planning and Review'

It has been determined that 32 CFR part 701, subparts F and G are not significant regulatory action. The rule does not:

(1) Have an annual effect to the economy of $100 million or more; or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or state, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof;

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Public Law 96–354, 'Regulatory Flexibility Act' (5 U.S.C. 601)

It has been certified that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Public Law 96–511, 'Paperwork Reduction Act' (44 U.S.C. Chapter 35)

It has been certified that this part does not impose any reporting or record keeping requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 32 CFR Part 701

Privacy.

Accordingly, Chapter I, 32 CFR part 701, is amended by adding subparts F and G to read as follows:

Subpart F—Department of the Navy Privacy Act Program

Sec.

Subpart G—Privacy Act Exemptions

Subpart F—Department of the Navy Privacy Act Program

Authority: Pub. L. 93–579, 88 Stat 1896 (5 U.S.C. 552a).

§ 701.100 Purpose.

Subparts F and G of this part implement the Privacy Act (5 U.S.C. 552a), and DoD Directive 5400.11,[1] and DoD 5400.11–R,[2] (32 CFR part 310) and provides Department of the Navy policies and procedures for:

(a) Governing the collection, safeguarding, maintenance, use, access, amendment, and dissemination of personal information kept by Department of the Navy in systems of records;

(b) Notifying individuals if any systems of records contain a record pertaining to them;

(c) Verifying the identity of individuals who request their records before the records are made available to them;

(d) Notifying the public of the existence and character of each system of records.

(e) Exempting systems of records from certain requirements of the Privacy Act; and

(f) Governing the Privacy Act rules of conduct for Department of the Navy personnel, who will be subject to criminal penalties for noncompliance with 5 U.S.C. 552a, as amended by the Computer Matching Act of 1988.

§ 701.101 Applicability.

This subpart and subpart G of this part apply throughout the Department of the Navy. It is also applicable to contractors by contract or other legally binding action, whenever a Department of the Navy contract provides for the operation of a system of records or portion of a system of records to accomplish a Department of the Navy function. For the purposes of any criminal liabilities adjudged, any contractor or any employee of such contractor is considered to be an employee of Department of the Navy. In case of a conflict, this subpart and subpart G of this part take precedence over any existing Department of the Navy directive that deals with the personal privacy and rights of individuals regarding their personal records, except for disclosure of personal information required by 5 U.S.C. 552 (1988) as amended by the Freedom of Information Reform Act and implemented by Secretary of the Navy Instruction 5720.42F,[3] 'Department of the Navy Freedom of Information Act Program.'

§ 701.102 Definitions.

For the purposes of this subpart and subpart G of this part, the following meanings apply.

Access. The review or copying of a record or parts thereof contained in a system of records by any individual.

Agency. For the purposes of disclosing records subject to the Privacy Act between or among Department of Defense (DoD) components, the Department of Defense is considered a single agency. For all other purposes, Department of the Navy is considered an agency within the meaning of Privacy Act.

[1] Copies may be obtained: http://www.whs.osd.mil/corres.htm.

[2] See footnote 1 to § 701.100.

[3] Copies may be obtained: Chief of Naval Operations, 2000 Navy Pentagon, Washington, DC 20350–2000.