August 26, 1997. We received six comments by that date. The comments were from a Canadian livestock producer, an organization representing the U.S. equine industry, a State Government official, a Canadian Government official, a U.S. senator, and a commenter who did not identify a particular affiliation. Five of the comments opposed closing the animal importation facilities at Derby Line, and two opposed closing the facilities at Champlain. The most common concern expressed in the comments was that, by closing either or both of these ports for animal inspection purposes, exporters and importers would have to transport their animals greater distances than is currently required, and additional travel time translates into higher transportation costs.

Since publication of the proposed rule of June 27, 1997, referenced above, our agency has become engaged in discussions with officials of the Animal Health Division of the Canadian Food Inspection Agency regarding the possibility of sharing animal inspection resources along the U.S.-Canada border. Because these discussions are ongoing, we believe that it would be premature to make the proposed changes to our animal and animal germ plasm inspection program along the U.S.-Canada border at this time. Accordingly, we have decided to withdraw the proposed rule. If, following the conclusion of our communications with Canadian animal health officials, we believe that it would be prudent to close the animal inspection facilities at any of the ports along the U.S.-Canada border, we will propose such changes in the **Federal Register** for public comment.

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 103–105, 111, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 10th day of August, 1998.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–22181 Filed 8–17–98; 8:45 am]

BILLING CODE 3410–34–P

FARM CREDIT ADMINISTRATION

12 CFR Ch. VI

Statement on Regulatory Burden

AGENCY: Farm Credit Administration.

ACTION: Notice of intent; request for comment.

SUMMARY: The Farm Credit Administration (FCA or Agency), through the FCA Board, is requesting commenters to identify regulations and policies that duplicate other requirements, are ineffective, or impose burdens that are greater than the benefits received. This action is being taken to improve the regulatory framework within which the Farm Credit System (FCS or System) operates.

DATES: Written comments should be received on or before November 20, 1998.

ADDRESSES: Comments may be mailed or delivered to Patricia W. DiMuzio, Director, Regulation and Policy Division, Office of Policy and Analysis, Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090 or sent by facsimile transmission to (703) 734–5784. Comments may also be submitted via electronic mail to ''reg-comm@fca.gov'' or through the Pending Regulations section of the FCA's interactive website at ''www.fca.gov.'' Copies of all communications received will be available for review by interested parties in the Office of Policy and Analysis, Farm Credit Administration.

FOR FURTHER INFORMATION CONTACT:

S. Robert Coleman, Senior Policy Analyst, Regulation and Policy Division, Office of Policy and Analysis, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4498,

or

Richard A. Katz, Senior Attorney, Regulatory Enforcement Division, Office of General Counsel, Farm Credit Administration, McLean, VA 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: The FCA is the independent Federal agency in the executive branch of the government responsible for regulating FCS institutions. As a Government-sponsored enterprise, the FCS primarily provides loans to farmers, ranchers, aquatic producers and harvesters, agricultural cooperatives, and rural utilities.

The FCA is committed to continually updating its regulations and policies so they remain useful to the FCS and the public without sacrificing safety and soundness. Our efforts to reduce regulatory burdens on FCS institutions are consistent with the National Performance Review (NPR), which seeks to eliminate regulations that unnecessarily impede the ability of businesses to compete efficiently in the marketplace. Although independent Federal agencies are not required to comply with the NPR, the FCA voluntarily participates in this program because FCA subscribes to its primary objectives.

This initiative is designed to meet the needs of the System for effective regulation as agricultural credit markets continually change. Our efforts to remove unnecessary regulatory requirements on the System began in 1993 when we initiated a project seeking comments on regulatory burden. *See* 58 FR 34003 (June 23, 1993). Many regulatory requirements have been eliminated or streamlined during the past 5 years in response to the above-referenced 1993 publication. More specifically, a rulemaking project in 1995 repealed several regulations that prescribed unnecessarily detailed managerial or operational practices at FCS institutions, or required System institutions to obtain FCA approval before they engaged in certain activities. *See* 60 FR 2552 (January 10, 1995); 60 FR 20008 (April 24, 1995). On November 24, 1995, the FCA published a notice in the **Federal Register** that informed the public of those regulations that the FCA decided to retain without amendment because they were determined necessary to implement the Farm Credit Act of 1971, as amended (Act), or to protect the safety and soundness of the System. *See* 60 FR 57913. Another rulemaking made technical corrections by: (1) Repealing other FCA prior-approval requirements; (2) conforming several regulations to recent statutory amendments; and (3) abolishing other burdensome regulatory requirements. *See* 61 FR 67181 (December 20, 1996). Additionally, the FCA responded to comments about regulatory burden by amending many regulations and policies, including:

- Related Services. *See* 60 FR 34090 (June 30, 1995);
- Ten-Day Notification Requirements for Changes in Interest Rates. *See* 61 FR 11303 (March 20, 1996);
- Capital Adequacy and Customer Eligibility. *See* 62 FR 4429 (January 30, 1997);
- Quarterly Reports to Shareholders. *See* 62 FR 15089 (March 31, 1997);
- Loan Underwriting Standards. *See* 62 FR 51007 (September 30, 1997); and,
- General Financing Agreements. *See* 63 FR 5721 (February 4, 1998).

In its continuing effort to update its regulations and policies, the FCA is soliciting comments from the public as to any of its regulations and policies that may duplicate other governmental requirements, are not effective in achieving stated objectives, or create a burden that is perceived to be greater than the benefits received. Although the Agency will strive to minimize

regulatory burden on the System, the FCA will ensure that safety and soundness is maintained and that its regulations and policies implement the Act.

Dated: August 11, 1998.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 98–22100 Filed 8–17–98; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 884, and 890

[Docket No. 98N–0564]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of any of the devices based on new information. This action implements certain statutory requirements.

DATES: Written comments by November 16, 1998; request for a change in classification by September 2, 1998. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), 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 recommendation 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 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 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 21 CFR part 807.

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see 21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The regulation; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. Section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C.