#### § 703.8 Prohibited fees.

- (a) A federal credit union's officials, senior management employees, and immediate family members of such individuals, may not receive pecuniary consideration in connection with the making of an investment by the federal credit union. The prohibition contained in this subsection also applies to any employee not otherwise covered if the employee is directly involved in investments or deposits unless the board of directors determines that the employee's involvement does not present a conflict of interest.
- (b) All transactions with business associates or family members not specifically prohibited by paragraph (a) of this section must be conducted at arm's length and in the interest of the credit union.

## § 703.9 Grandfather provisions.

- (a) Subject to safety and soundness considerations, a federal credit union's authority to hold an investment is governed by the regulations in effect at the time of purchase. Past regulations governing certain investments are described in paragraphs (b) through (d) of this section.
- (b) Subject to safety and soundness considerations, a federal credit union may hold a fixed-rate CMO/REMIC purchased:
  - (1) Before December 2, 1991;
- (2) On or after December 2, 1991, but before July 30, 1993, if its average life does not extend or shorten by more than 6 years if interest rates rise or fall 300 basis points; or
- (3) On or after December 2, 1991, but before the effective date of the final regulation, if for the purpose of reducing interest rate risk.
- (c) Subject to safety and soundness considerations, a federal credit union may hold a variable-rate CMO/REMIC purchased:
  - (1) Before December 2, 1991;
- (2) On or after December 2, 1991, but before July 30, 1993, if:
- (i) The interest rate is reset at least annually;
- (ii) The maximum allowable interest rate on the instrument is at least 300 basis points above the interest rate of the instrument at the time of purchase; and
- (iii) The interest rate of the instrument varies directly (not inversely) with the index upon which it is based and is not reset as a multiple of the change in the related index; or
- (3) On or after July 30, 1993, but before the effective date of this regulation, if:
- (i) The interest rate is reset at least annually;

- (ii) The maximum allowable interest rate on the instrument is at least 300 basis points above the interest rate of the instrument at the time of purchase; and
- (iii) The interest rate of the instrument varies directly (not inversely) with the index upon which it is based and is not reset as a multiple of the change in the related index; and
- (iv) The estimated change in its price is 17 percent or less, due to an immediate and sustained parallel shift in the yield curve of plus or minus 300 basis points.
- (d) Subject to safety and soundness considerations, a federal credit union may hold a CMO/REMIC residual, SMBS, or zero coupon security with a maturity greater than 10 years, if the investment was purchased:
  - (1) Before December 2, 1991; or
- (2) On or after December 2, 1991, but before the effective date of the final regulation, if for the purpose of reducing interest rate risk.
- (e) All grandfathered investments are subject to the reporting and risk management requirements of § 703.3.

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# Food And Drug Administration

## 21 CFR Part 872

[Docket No. 95N-0298]

Dental Devices; Effective Date of Requirement for Premarket Approval of Partially Fabricated Denture Kits

**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 partially fabricated denture kits. The agency is also summarizing its proposed findings regarding the benefits to the public from use of the device as well as the degree of risk of illness or injury intended to be eliminated or reduced by requiring that the device have an approved PMA or a completed PDP. In addition, FDA is announcing an opportunity for interested persons to request the agency to change the classification of the device based on new information.

**DATES:** Written comments by February 27, 1996; requests for a change in classification by December 14, 1995. FDA intends that if a final rule based on this proposal is issued, PMA's or notices of completion of PDP'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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Louis Hlavinka, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8879.

## SUPPLEMENTARY INFORMATION:

## I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to the devices that were on the market on or after that date as 'preamendments devices.'

Section 515(b)(1) of the act (21 U.S.C.)360e(b)(1)) establishes 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 notice of completion of a PDP until 90 days after FDA promulgates 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, such a device is exempt from the investigational device exemption (IDE) requirements (part 812 (21 CFR part 812)) until the date stipulated by FDA in the final rule requiring the submission of a PMA application or a notice of completion of a PDP for that device. At that time, an IDE must be submitted only if a PMA has not been submitted or a PDP not completed.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval