the investigational device exemption (IDE) regulations in 21 CFR part 812 until the date stipulated by FDA in the final rule requiring the submission of a premarket approval application or a PDP for that device. At that time, an IDE must be submitted only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides that 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 proposed rule; (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 of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, 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. 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 made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). FDA has in the past requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for OTC denture cushions or pads and OTC denture repair kits.

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that ''the thirty month grace period afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval.'' (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976).)

A. Classification of OTC Denture Cushions or Pads and OTC Denture Repair Kits

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying the OTC denture cushion or pad and the OTC denture repair kit into class III. The preamble to the proposal to classify the device published in the **Federal Register** of December 30, 1980 (45 FR 85962), included the recommendation of the Dental Devices Panel (the panel), an FDA advisory committee, regarding the classification of the devices. The panel recommended that the OTC denture cushion or pad be in class III (premarket approval) if the device is made of a material different from wax-impregnated cotton cloth, and if it is intended for a use other than short-term use. The 1980 panel recommended that the OTC denture repair kit be in class III (premarket approval) for all uses. The panel believed that general controls and performance standards would not provide reasonable assurance of the safety and effectiveness of these devices and that there was insufficient information to establish such a standard.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval for 31 class III preamendments devices. Among other things, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. The OTC denture cushion or pad and the OTC denture repair kit were not included in the list of devices identified in that notice. However, using those factors, FDA updated its priorities in a preamendments class III devices strategy document made public through a **Federal Register** Notice of Availability published May 6, 1994 (59 FR 23731). Accordingly, FDA has recently determined that the OTC denture cushion or pad identified in 21 CFR 872.3540 and the OTC denture repair kit identified in 21 CFR 872.3570 have a high priority for initiating a proceeding to require premarket approval because the safety and effectiveness, of the devices have not been established by valid scientific evidence as defined in 21 CFR 860.7. Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the OTC denture cushion or pad and the OTC denture repair kit have approved PMA's or declared completed PDP's.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the OTC denture cushion or pad and the OTC denture repair kit within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the OTC denture cushion or pad and the OTC denture repair kit during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period of a PMA beyond 180 days unless the agency finds that