''* * * the continued availability of the device is necessary for the public health.''

FDA intends that, under § 812.2(c)(2), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any OTC denture cushion or pad and OTC denture repair kit which is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA, notice of completion of a PDP, or an IDE application for the OTC denture cushion or pad and OTC denture repair kit is not submitted to FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. FDA, therefore, cautions that, for manufacturers not planning to submit a PMA immediately, IDE applications should be submitted to FDA at least 30 days before the end of the 90 day period after the final rule is published to minimize the possibility of interrupting all availability of the device. FDA does not consider an investigation of the OTC dental cushion or pad and the OTC denture repair kit to pose a significant risk as defined in the IDE regulation. The device may be distributed for investigational use if manufacturers, importers or other sponsors comply with the abbreviated requirements (21 CFR 812.1(b)) of theIDE regulation.

C. Description of Devices

An OTC denture cushion or pad is a prefabricated or noncustom device that is intended to improve the fit of a loose or uncomfortable denture, and may be available for purchase over-the-counter. It is a class I device if the OTC denture cushion or pad is made of wax-impregnated cotton cloth that the patient applies to the base or inner surface of a denture before inserting the denture into the mouth, and is intended to be discarded following 1 day of use. It is a class III device if the product is made of a material other than wax-impregnated cotton cloth, if it is not intended to be discarded after 1 day's use, and it is intended for a use other than short-term use.

An OTC denture repair kit is a device consisting of a material, such as a resin monomer system of powder and liquid glues, that is intended to be applied permanently to a denture to mend cracks or breaks. The device may by available for purchase OTC.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the OTC denture cushion or pad and the OTC denture repair kit to have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the device.

E. Risk Factors

1. OTC Denture Cushions or Pads

OTC denture cushions or pads have been associated with changes in oral tissues, including tissue irritation, erythema, and bone resorption (due to the uneven pressure caused by the cushion and pad) (Ref. 1). There is also a risk of sensitivity to the cushion or pad material. Additionally, in 1980, the panel associated a potential unreasonable risk of illness or injury with OTC denture cushions or pads. The denture cushions or pads may cause an improper vertical dimension of a denture (Ref.2), which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution). The panel also believed that long-term irritation of oral tissue caused by incorrect vertical dimension could cause the formation of carcinomas. There is no recent evidence in the published scientific literature to suggest that these risks are no longer relevant.

2. OTC Denture Repair Kits

OTC denture repair kits may cause: Altered esthetics, contact dermatitis, soft tissue irritation (resulting from the use of commercially available cements or adhesives not specifically designed for intraoral use), and an ill fitting denture (Refs. 3, 4, 5, and 6). The 1980 Dental Devices Classification panel believed that OTC denture repair kits presented a potential unreasonable risk of illness or injury. The panel advised that if the repaired denture does not have the same characteristics and fit as the original denture, the repaired denture may cause a change in the vertical dimension of the denture, which may result in increased occlusal (biting) forces and lead to bone loss through resorption (degeneration of the bone through gradual dissolution) (Refs. 5 and 7). The panel also believed that long-term irritation of oral tissue caused by incorrect vertical dimension could cause the formation of carcinomas. There is no new evidence in the published scientific literature to suggest that these risks are no longer relevant.

F. Benefits of the Devices

1. OTC Denture Cushion or Pad

OTC denture cushions or pads are placed on the tissue contacting surface of a denture to help fill in areas where the acrylic denture material no longer contacts the oral tissue. The potential benefits intended from the use of an OTC denture cushion or pad are improvement in the retention, stability, and comfort of maxillary and mandibular dentures.

2. OTC Denture Repair Kit

An OTC denture repair kit provides the material for repairing cracks or breaks in a denture, or for reattaching dislodged teeth on a denture to the actual consumer. The denture repair kit restores the function and esthetics of a denture so that the denture can continue to be worn.

G. Need for Information for Risk/Benefit Assessment of the Device

FDA classified the OTC denture cushion or pad and the OTC denture repair kit into class III because FDA determined that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has determined that the special controls that may now be applied to class II devices under the Safe Medical Devices Act of 1990 also would not provide such assurance. FDA has weighed the probable risks and benefits to the public health from the use of the devices and believes that the literature reports and other information discussed above suggest the potential for unreasonable risks associated with use of the devices. These risks must be addressed by the manufacturers of OTC denture cushions or pads and OTC denture repair kits. FDA believes that OTC cushions or pads and OTC denture repair kits should undergo premarket approval to establish effectiveness and to determine whether the benefits to the patient are sufficient to outweigh any risk.

II. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act and § 814.20 (21 CFR 814.20) of the procedural regulations for PMA's. Such a PMA should also include