

fumigators would be considered small by SBA standards.

In FY 1993, approximately 37,800 pounds of methyl bromide was used to fumigate brassware products from India. Based on this figure, exempting Indian brassware products from fumigation, which costs approximately \$1.50 a pound, would result in fumigators as a group losing about \$56,700 a year in sales of methyl bromide. The contractor charges for methyl bromide and labor are approximately \$275 per fumigation. In addition, those fumigators would also lose the unloading and loading charges of approximately \$500 per fumigation. At the Long Beach, CA, port of entry the approximate annual revenue of methyl bromide fumigators for brassware fumigations was \$337,400. Long Beach comprises 37.7 percent of the national brassware fumigations. Using the Long Beach estimate as a base, methyl bromide fumigators may lose approximately \$894,960 on brassware fumigations nationwide.

Information on the number of importers of brassware from Bombay, India, is unavailable. Domestic importers would save on the treatment costs. The treatment costs include the charges of methyl bromide fumigators and overtime costs for APHIS inspectors during fumigations. In Long Beach, CA, the annual overtime charges are approximately \$37,400. Using the Long Beach estimate as a base, overtime charges nationwide would be approximately \$100,000 annually. As a group, importers would save about \$1 million a year in overtime and contractor charges.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, 7 CFR part 319 would be amended as follows:

PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151-167, and 450; 21 U.S.C. 136 and 136a; 7 CFR 2.17, 2.51, and 371.2(c).

§ 319.75-2 [Amended]

2. Section 319.75-2 would be amended by removing paragraph (a)(2) and by redesignating paragraphs (a)(3) through (a)(8) as (a)(2) through (a)(7), respectively.

§ 319.75-4 [Amended]

3. In § 319.75-4, paragraph (a) introductory text would be amended by removing the words "Brassware; wooden screens; goatskins;" and by adding the word "Goatskins;" in their place.

Done in Washington, DC, this 30th day of June 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95-16886 Filed 7-10-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N-0034]

Dental Devices; Effective Date of Requirement for Premarket Approval of Over-the-Counter (OTC) Denture Cushions or Pads and OTC Denture Repair Kits

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

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 product development protocol (PDP) for OTC denture cushions or pads and OTC denture repair kits. The agency is also summarizing its 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 devices have an approved PMA or a completed PDP. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information.

DATES: Submit written comments by October 10, 1995; requests for a change in classification by July 26, 1995. FDA intends that if a final rule based on this proposed rule 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 before May 28, 1976, and the substantially equivalent devices that were marketed 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 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, such a device is exempt from

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

“* * * 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 the IDE 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 be 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

a detailed discussion of the risks identified above, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that reasonably should be known to the applicant that have not been identified in this document; (2) the effectiveness of the specific OTC denture cushion or pad and OTC denture repair kit that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence as defined in 21 CFR 860.7 and should be obtained from well-controlled clinical studies, with detailed data, in order to provide reasonable assurance of the safety and effectiveness of the OTC denture cushion or pad and the OTC denture repair kit for their intended uses. In addition to the basic requirements described in § 814.20(b)(6)(ii) for a PMA, it is recommended that such studies employ a protocol that meets the following criteria. Applicants should submit any PMA in accordance with FDA's "Guideline for the Arrangement and Content of a PMA Application." The guideline is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), 1350 Piccard Dr., Rockville, MD 20850.

A. General Protocol Requirements

The OTC denture cushion or pad or OTC denture repair kit should be evaluated in a prospective, randomized, controlled clinical trial that uses adequate controls. The study must attempt to answer all of the general and specific questions about the safety and effectiveness of the devices, including the risk to benefit ratio. These questions should relate to the pathophysiological effects which the device produces, as well as the primary and secondary variables analyzed to evaluate safety and effectiveness. Study endpoints and study success must be defined.

Animal toxicity studies should be conducted according to the International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing", specifically:

1. The selection of material(s) to be used in device manufacture and its toxicological evaluation should initially take into account full characterization of the material, for example, formulation, known and suspected impurities and processing.

2. The material(s) of manufacture, the final product and possible leachable chemicals or degradation products should be considered for their relevance to the overall toxicological evaluation of the device.

3. Any in vitro or in vivo experiments or tests must be conducted according to recognized good laboratory practices followed by an evaluation by competent informed persons.

4. Any change in chemical composition, manufacturing process, physical configuration or intended use of the device must be evaluated with respect to possible changes in toxicological effects and the need for additional toxicity testing.

5. The toxicological evaluation performed in accordance with the guidance should be considered in conjunction with other information from other nonclinical tests, clinical studies, and postmarket experiences for an overall safety assessment.

Examples of questions to be addressed by the clinical studies may include the following:

1. What morbidity (erythema, edema, soft tissue hyperplasia, ulceration, allergic response, bone resorption, or other adverse effects) is associated with the subject device in the patient population and how does this compare to the control?

2. Is the material composition of the device compatible with the denture base material?

3. Can the average consumer follow the instructions for use included with the device and adequately restore the function of the denture?

4. What impact does the device have on the vertical dimension of occlusion?

5. What are the long term effects of the device on the oral tissue?

6. What changes in the physical characteristics (hardness, dimensional stability) of the materials take place over time?

7. Does the device provide a functional level of retention for the user?

8. Does the device allow sufficient comfort for the user?

9. Does the denture repair kit provide adequate strength for the denture to function properly following temporary repair?

Statistically valid investigations should include a clear statement of the objectives of the study. Appropriate rationale, supported by background literature on previous uses of the device and proposed mechanisms for its effect, should be presented as justification of the questions to be answered, and the definitions of study endpoints and success. Clear study hypotheses should

be formulated based on this information.

B. Study Sample Requirements

The subject population should be well defined. Ideally, the study population should be as homogeneous as possible in order to minimize selection bias and reduce variability. Otherwise, an excessively large population may be necessary to achieve statistical significance. Independent studies producing comparable results at multiple study sites using identical protocols are necessary to demonstrate repeatability. Justification must be provided for the sample size used to show that a sufficient number of patients were enrolled to attain statistically and clinically meaningful results. Eligibility criteria for the subject population should include the subjects' potential for benefit, the ability to detect a benefit in the subject, the absence of both contraindications and any competing risks, and assurance of subject compliance. In a heterogeneous sample, stratification of the patient groups participating in the clinical study may be necessary to analyze homogeneous subgroups and thereby minimize potential bias. All endpoint variables should be identified, and a sufficient number of patients from each subgroup analysis should be included to allow for stratification by pertinent demographic characteristics.

The investigation should include an evaluation of comparability between treatment groups and control groups (including historical controls). Baseline (e.g., age, gender, etc.) and other variables should be measured and compared between the treatment and control groups. The baseline variables should be measured at the time of treatment assignment, not during the course of the study. Other variables should be measured during the study as needed to completely characterize the device's safety and effectiveness.

C. Study Design

All potential sources of error, including selection bias, information bias, misclassification bias, comparison bias, or other potential bias should be evaluated and minimized. The study should clearly measure any possible placebo effect. Treatment effects should be based on objective measurements. The validity of these measurement scales should be shown to ensure that the treatment effect being measured reflects the intended uses of the devices.

Adherence to the protocol by subjects, investigators, and all other individuals involved is essential and requires monitoring to assure compliance by

both patients and physicians. Subject exclusion due to dropout or loss to followup greater than 20 percent may invalidate the study due to bias potential; therefore, initial patient screening and compliance of the final subject population will be needed to minimize the dropout rate. All dropout must be accounted for and the circumstances and procedures used to ensure patient compliance must be well documented.

Endpoint assessment cannot be based solely on a statistical value. Instead, the clinical outcome, must be carefully defined to distinguish between the evaluation of the proper function of the device versus its benefit to the subject. Statistical significance and effectiveness of the device must be demonstrated by the statistical results. However, under certain restricted circumstances, a clinically significant result may be acceptable without statistical significance.

Observation of all potential adverse effects must be recorded and monitored throughout the study and the followup period. All adverse effects must be documented and evaluated.

D. Statistical Analysis Plan

The involvement of a biostatistician is recommended to provide proper guidance in the planning, design, conduct, and analysis of a clinical study. There must be sufficient documentation of the statistical analysis and results including: Comparison group selection, sample size justification, stated hypothesis test(s), population demographics, study site pooling justification, description of statistical tests applied, clear presentation of data and a clear discussion of the statistical results and conclusions.

In addition to this generalized guidance, the investigator or sponsor is expected to incorporate additional requirements necessary for a well-controlled scientific study. These additional requirements are dependent on what the investigator or sponsor intends to measure or what the expected treatment effect is based on each device's intended use.

E. Clinical Analysis

The analysis which results from the study should include a complete description of all the statistical procedures employed, including assumption verification, pooling justification, population selection, statistical model selection, etc. If any procedures are uncommon or derived by the investigator or sponsor for the specific analysis, an adequate

description must be provided of the procedure for FDA to assess its utility and adequacy. Data analysis and interpretation from the clinical investigation should relate to the medical claims.

F. Monitoring

Rigorous monitoring is required to assure that study procedures are followed and that data are collected in accordance with the study protocol. Forceful monitors, who have appropriate credentials and who are not aligned with patient management or otherwise biased, contribute prominently to a successful study.

III. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the OTC denture cushion or pad and the OTC denture repair kit are to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by July 26, 1995.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the OTC denture cushion or pad or the OTC denture repair kit is submitted, the agency will, by September 11, 1995, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons

between 9 a.m. and 4 p.m., Monday through Friday.

(1) Cinotti, W. R., et al., "An Over-the-Counter Dental Cushion: A Study of Efficacy, Safety, and Compliance," vol. v, no. 10, pp. 792-801, "The Compendium of Continuing Education," November/December 1984.

(2) Craig, R. G., et al., "Dental Materials Properties and Manipulation," 5th ed., Mosby, pp. 282-283, 1992.

(3) Kapur, K. K., "A clinical evaluation of denture adhesives," *Journal of Prosthetic Dentistry*, 10(6):550-558, 1967.

(4) Koudelka, B. M., et al., "Denture self-repair: Experimental soft tissue response to selected commercial adhesives," *Journal of Prosthetic Dentistry*, 43(2):143-148, 1980.

(5) Ortman, L. F., "Patient Education and Complete Denture Maintenance," *Symposium on Complete Dentures, Dental Clinics of North America*, 21(2):359-367, 1977.

(6) Phillips, R. W., "Elements of Dental Materials for Dental Hygienists and Assistants," 3d ed., W. B. Saunders, pp. 138-139, 1977.

(7) Woelfel, J. B., et al., "Additives sold over the counter dangerously prolong wearing period of ill-fitting dentures," *Journal of the American Dental Association*, 71(9):603-613, 1965.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environment assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because these devices have been classified into class III since August 12, 1987, and manufacturers of

these devices that were legally in commercial distribution before May 28, 1976, or found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may, on or before October 10, 1995, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before July 26, 1995, submit to the Dockets Management Branch a written request to change the classification of the OTC denture cushion or pad or the OTC denture repair kit. Two copies of any request are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 872.3540 is amended by revising paragraph (c) to read as follows:

§ 872.3540 OTC denture cushion or pad.

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(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any OTC denture cushion or pad made of a material other than wax-

impregnated cotton cloth, not intended to be discarded after 1 day's use, and intended for a use other than short-term use, that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to an OTC denture cushion or pad made of a material other than wax-impregnated cotton cloth, not intended to be discarded after 1 day's use, and intended for a use other than short-term use that was in commercial distribution before May 28, 1976. Any other OTC denture cushion or pad made of a material other than wax-impregnated cotton cloth, not intended to be discarded after 1 day's use, and intended for a use other than short-term use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

3. Section 872.3570 is amended by revising paragraph (c) to read as follows:

§ 872.3570 OTC denture repair kit.

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(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any OTC denture repair kit that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the OTC denture repair kit that was in commercial distribution before May 28, 1976. Any other OTC denture repair kit shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: June 26, 1995.

Joseph A. Levitt,

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 264 and 265

[FRL-5227-1]

Hazardous Waste Management: Liquids in Landfills

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking to grant a petition.

SUMMARY: On November 18, 1992, the Agency promulgated a final rule on liquids in landfills. That rule satisfied a statutory requirement in the Resource Conservation and Recovery Act (RCRA) as amended by the Hazardous and Solid Waste Amendments of 1984 regarding the landfill disposal of containerized liquids. Specifically, the statute required EPA to issue a rule that prohibited the disposal in hazardous waste landfills of liquids that have been absorbed in materials that biodegrade. Today's proposed rulemaking, which provides increased flexibility to the regulated community, would add an additional test to demonstrate that a sorbent is non-biodegradable.

In the final rules section of this **Federal Register**, EPA is promulgating a direct final rule without prior proposal because EPA views this as minor technical modification that merely broadens the scope of the testing. A detailed rationale for the amendment is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

DATES: Written comments on this proposed rule must be received by August 10, 1995.

ADDRESSES: Written comments (one original and two copies) should be addressed to: EPA RCRA Docket No. F-95-ALLP-FFFFF, room M2616, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The docket is open from 9 a.m. to 4 p.m., Monday through Friday, except Federal holidays. Call 202-260-9327 for an appointment to examine the docket. Up to 100 pages may be copied free of charge from any one regulatory docket. Additional copies are \$0.15 per page.