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.

* * * * *

(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.

* * * * *

(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.