

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0274]

Denture Cleaners, Adhesives, Cushions, and Repair Materials; Revocation of Compliance Policy Guide 7124.05

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled “Sec. 315.200 Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG 7124.05).” This CPG is no longer necessary because the agency has classified these products as devices.

DATES: The revocation is effective [*insert date 30 days after date of publication in the Federal Register*].

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 (301-827-0411) or fax your request to 301-827-0482.

A copy of the CPG may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory

Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD
20857, 301-827-0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled “Sec. 315.200 Status of Dental Supplies such as Denture Cleaners, Adhesives, Cushions, and Repair Materials as a Device or Cosmetic (CPG 7124.05)” on April 26, 1976. This CPG, as revised on August 9, 1988, considered these products to be devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(h)).

In accordance with section 513 of the act (21 U.S.C. 360c), the agency has classified dental products as devices by regulation, including but not limited to:

1. Karaya and sodium borate with or without acacia denture adhesive (21 CFR 872.3400)
2. Ethylene oxide homopolymer and/or carboxymethylcellulose sodium denture adhesive (21 CFR 872.3410)
3. Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive (21 CFR 872.3420)
4. Ethylene oxide homopolymer and/or karaya denture adhesive (21 CFR 872.3450)
5. Polyacrylamide polymer (modified cationic) denture adhesive (21 CFR 872.3480)
6. Carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (21 CFR 872.3490)

7. Polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive (21 CFR 872.3500)

8. Over-the-counter (OTC) denture cleanser (21 CFR 872.3520)

9. Mechanical denture cleaner (21 CFR 872.3530)

10. OTC denture cushion or pad (21 CFR 872.3540)

11. OTC denture repair kit (21 CFR 872.3570)

12. Denture relining, repairing, or rebasing resin (21 CFR 872.3760)

Given these device classifications, FDA is revoking CPG 7124.05, in its entirety, to eliminate unnecessary compliance policy.

II. Electronic Access

Prior to [*insert date 30 days after date of publication in the **Federal Register***], a copy of the CPG may also be downloaded to a personal computer

with access to the Internet. The Office of Regulatory Affairs (ORA) home page includes the referenced document that may be accessed at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg315-200.html.

Dated: 111111111111

11111111111111111111

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S