CPG Sec. 315.100 Illegal Interstate Commercial Shipment of Dentures (CPG retitled and revised 5/19/2005)

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This document supersedes Compliance Policy Guide (CPG) “Sec. 315.100 Dentures; Sale in Interstate Commerce of Dentures by Persons not Licensed to Practice Dentistry (CPG 7124.07)” that was issued in August 1996.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs
Office of Enforcement
Division of Compliance Policy

Preface
Public Comment:

At any time, interested persons may submit written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comments are to be identified with the title of this guidance document. Such comments will be considered when determining whether to amend the current guidance. For questions regarding the use or interpretation of this guidance, contact Jeffrey Governale at 240-632-6851.

Additional Copies:

Submit written requests for a single copy of this guidance to the Division of Compliance Policy (HFC-230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-001, or FAX your request to 240-632-6861. A copy of the guidance may also be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs’ home page includes the guidance and may be accessed at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg315-100.html.

Compliance Policy Guide Guidance

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.
FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required.

Sub Chapter 315 Dental
Sec. 315.100 *Illegal Interstate Commercial Shipment* of Dentures (CPG 7124.07)
BACKGROUND:

The Federal Denture Act *of 1942* (Section 1821 of Title 18 *of the United States Code (18 USC 1821)) is *enforced by the Department of Justice.* This law was amended in 1996 (Public Law (PL) 104-294) and 2002 (PL 107-273) and reads* as follows:

"S1821. Transportation of dentures

Whoever transports by mail or otherwise to or within the District of Columbia or any Possession of the United States or uses the mails or any instrumentality of interstate commerce for the purpose of sending or bringing into any State or Territory any set of artificial teeth or prosthetic dental appliance or other denture, constructed from any cast or impression made by any person other than, or without the authorization or prescription of, a person licensed to practice dentistry under the laws of the place into which such denture is sent or brought, where such laws prohibit;

1. the taking of impressions or casts of the human mouth or teeth by a person not licensed under such laws to practice dentistry;
2. the construction or supply of dentures by a person other than, or without the authorization or prescription of, a person licensed under such laws to practice dentistry; or
3. the construction or supply of dentures from impressions or casts made by a person not licensed under such laws to practice dentistry -

   Shall be fined *under this title* or imprisoned not more than one year, or both."

REGULATORY ACTION GUIDANCE:

Reports of violations of the Federal Denture Act should *first* be referred to the *local office of the Office of Criminal Investigations (OCI)* for review. *After consulting with the Center for Devices and Radiological Health's Office of Compliance (CDRH/OC), the OCI may refer the matter to the

appropriate United States Attorney for consideration for criminal prosecution or to CDRH/OC. The latter office may take appropriate non-criminal action for any violations of the Federal Food, Drug, and Cosmetic Act or refer the report to state or local regulatory authorities.*

Material between asterisks is new or revised

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More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

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Chapter 4 - Human Drugs (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119572.htm)

Chapter 5 - Food, Colors, and Cosmetics (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm)

Chapter 6 - Veterinary Medicine (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm117042.htm)