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Effective Date	12-23-99
Officer	<i>[Signature]</i>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-5002]

Acupuncture Devices and Accessories; Revocation of Compliance Policy Guide

7124.11

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the Compliance Policy Guide (CPG) entitled "Sec. 305.100 Acupuncture Devices and Accessories (CPG 7 124.11)" to eliminate obsolete compliance policy. In general, this CPG no longer reflects current agency policy because acupuncture needles have been reclassified from class III to class II (special controls).

DATES: 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. 305.100 Acupuncture Devices and Accessories (CPG 7 124.11)” on June 15, 1976. This CPG considered acupuncture devices and accessories as investigational devices subject to the investigational device exemptions (IDE) regulations (21 CFR part 812). As such, these class III devices were permitted to be distributed only for the purpose of conducting clinical studies to establish their safety and effectiveness. In the absence of an approved premarket approval application, the sale, promotion, and commercial distribution of these acupuncture devices and accessories were prohibited.

In response to a reclassification petition that was submitted to FDA by the Acupuncture Coalition, the agency reclassified acupuncture needles from class III to class II (special controls) in the **Federal Register** of December 6, 1996 (61 FR 64616). The classification regulation (21 CFR 880.5580) for solid, stainless steel, acupuncture needles requires that these class II devices must comply with special controls for single use labeling, prescription labeling, biocompatibility, and sterility.

Currently, an acupuncture needle that is intended to pierce the skin in the practice of acupuncture may be commercially distributed if it is the subject of a cleared premarket notification (510(k)), complies with the special controls, and meets all other applicable statutory and regulatory requirements.

Given the reclassification of acupuncture needles, FDA is revoking CPG 7124.11, in its entirety, to eliminate obsolete 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/cpg305-100.html>.

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LOC*

Dated: 12-7-99
December 7, 1999



Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL
Jim Windsor

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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