

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1990D-0194]

Radioimmunoassay Analysis of Hair to Detect the Presence of Drugs of Abuse; Revocation of Compliance Policy Guide 7124.06

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the compliance policy guide (CPG) entitled "Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06)." This CPG no longer reflects current agency policy.

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

ADDRESSES: Submit written requests for single copies of CPG 7124.06 to the Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301-827-0482.

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

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Division of Compliance Policy (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued the CPG entitled “Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06)” on May 31, 1990. The CPG stated that the use of radioimmunoassay (RIA) to analyze hair for the presence of drugs of abuse lacked scientific evidence of its safety and effectiveness, as defined in 21 CFR 860.7. Accordingly, the CPG indicated that approved premarket approval applications (PMAs) were necessary before commercially distributing these types of devices.

Since publication of this CPG, more than 88 scientific articles on drugs of abuse testing in hair have been published in the peer-reviewed scientific literature. There has been extensive discussion about the analytical performance, the clinical parameters, and sources of error and testing differences for this technology compared to other technologies. FDA has reviewed a number of hair tests and found these to be substantially equivalent to predicate devices measuring drugs of abuse in other matrices. Given these scientific developments and product clearances, FDA is revoking CPG 7124.06, in its entirety, to eliminate obsolete compliance policy.

Any person who proposes to introduce into commercial distribution an in vitro diagnostic device that is intended to test human hair for drugs of abuse is required to submit a premarket notification (510(k)) to FDA. However, in accordance with § 864.3260 (21 CFR 864.3260), over-the-counter test sample collection systems for drugs of abuse testing (systems sold for use in nonmedical settings such as insurance, workplace, and home) are exempt from the 510(k) submission requirement as long as the laboratory test (whether for urine, hair, or other matrices) has been cleared or approved by FDA, the

laboratory is recognized as capable of performing the testing, and the system is properly labeled. (See 21 CFR 809.40 and § 864.3260.)

Dated: December 23, 2003.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

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