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Sec. 370.200 RIA Analysis of Hair to Detect the Presence of Drugs of Abuse (CPG 7124.06) BACKGROUND:

There is a growing interest in testing for drugs of abuse in the work place as well as in law enforcement. It is the agency's position that the apparatus and reagents associated with these tests are medical devices as that term is defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)). One testing method currently being offered is the analysis of hair by radioimmunoassay (RIA) for evidence of the use of drugs of abuse. The Food and Drug Administration (FDA) has been asked to assess the validity, accuracy and effectiveness of RIA of hair for the detection of drugs of abuse. FDA is concerned that businesses may begin distributing kits for which efficacy has not been established for the purpose of testing hair for the presence of drugs of abuse.

Hair analysis for drugs of abuse as addressed in this guide refers to any RIA "in vitro" test procedure for the detection of drugs of abuse by hair analysis similar to those initially reported by Baumgartner in 1979. 1

The procedure is represented as capable of identifying, from the RIA analysis of a hair sample, specific drugs of abuse over time, dating from the present back for months to possibly years. Over the past several years a number of experts, including FDA scientists, have reviewed the published literature on RIA hair analysis for drugs of abuse and have concluded that the test is unproven. (See references)

FDA's review of agency records shows that there is no FDA regulated product on the market that has been demonstrated to be effective in RIA analysis of hair for the presence of drugs of abuse nor has any manufacturer submitted evidence to support the marketing of any new product for this purpose.

It is FDA's view that RIA hair analysis for the presence of drugs of abuse is an unproven procedure unsupported by the scientific literature or well-controlled studies and clinical trials. The consensus of scientific opinion is that hair analysis by RIA for the presence of drugs of abuse is unreliable and is not generally recognized by qualified experts as effective.

POLICY:

FDA has determined that any RIA in vitro diagnostic (IVD) device intended, promoted, or offered, to test a specimen of a person's hair to detect whether the person has used a drug of abuse:

1. is a medical device under section 201(h) of the Act,
2. lacks valid scientific evidence of safety and effectiveness as defined in 21 CFR 860.7,
3. is a device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of the amendments (May 28, 1976), and
4. is intended for a new use, testing a specimen of a person's hair to detect a person's use of a drug of abuse, which use is not substantially equivalent to the use of an IVD device marketed before the enactment date of the amendments.

Accordingly, in FDA's view, a RIA IVD, intended to test a specimen of a person's hair to

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detect whether the person has used a drug of abuse, that is introduced into commercial distribution without an approved PMA, is:

1. Adulterated under section 501(f)(1)(B), in that the device is classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, which does not have such an approved application in effect, and which is not exempt from section 515(a) under the investigational device exemption (IDE) provisions of section 520(g);
2. Misbranded under section 502(f)(1), in that the device fails to bear adequate directions for use and is not exempt under 21 CFR 801.109 Prescription Devices, because information cannot be provided under which practitioners can use the device safely and for the aforesaid purpose.

SCOPE:

This policy applies to any RIA in vitro diagnostic (IVD) intended to test a specimen of a person's hair to detect whether the person has used a drug of abuse. It does not apply to mass spectrophotometer or gas chromatograph analysis of hair samples.

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