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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-1273]

Medical Devices; Draft Guidance for FDA Staff on Civil Money Penalty Policy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for FDA Staff on Civil Money Penalty Policy." The civil money penalty (CMP) policy is intended for use by all FDA Regional and District Directors for the purpose of advising their field personnel when considering potential CMP recommendations under the Safe Medical Devices Act of 1990 (SMDA).

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for FDA Staff on Civil Money Penalty Policy" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this guidance must be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea P. Latish, Center for Devices and Radiological Health (HFZ-330), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4611.

SUPPLEMENTARY INFORMATION:

I. Background

The SMDA amended section 303(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 333(f)) to authorize FDA to impose CMP actions for all violations of the act involving medical devices except for current good manufacturing practice (CGMP) and medical device report violations that do not constitute a significant or knowing departure from such requirements or a risk to public health, filth violations in devices that are not otherwise defective, and minor violations for tracking and reports of corrections and removals. Thus, FDA has considerable latitude when applying CMP to violations involving devices.

FDA has developed a package of three documents that set forth the agency's policy concerning the application of civil money penalties for violations of the act involving medical devices. The three draft guidance documents are: "Application of the Safe Medical Devices Act Civil Money Penalty Policy," "Safe Medical Devices Act Civil Money Penalty Fee Matrix," and "Safe Medical Devices Act Civil Money Penalty Decision Tree."

The "Application of the Safe Medical Devices Act Civil Money Penalty Policy" outlines the use of the CMP for CGMP and premarket notification (510(k)) violations for chronic and repeat violators, and for less significant violations. It also discusses the relationship between CMP and seizure or injunction. The "Safe Medical Devices Act Civil Money Penalty Decision Tree" outlines whether the evidence and information collected justifies pursuing a CMP case. It is not an all-inclusive list of every issue that should be considered, but rather a series of questions to guide FDA's decision. The "Safe Medical Devices Act Civil Money Penalty Fee Matrix" is a procedure for calculating the penalty amount that will be assessed. The schedule set forth in the matrix covers the statutory factors that FDA is required to evaluate under the SMDA in determining

the appropriateness of the case. The matrix will help to ensure consistency in the assessment of a CMP.

FDA is making these three draft guidance documents available to all FDA Regional and District Directors for the purposes of advising field personnel. FDA is announcing the availability of these documents to the public in order to advise persons who may be affected by FDA's policy and to obtain comment on whether the policy should be revised.

This guidance package of three documents takes into consideration the Presidential Memorandum, dated April 21, 1995, and the Small Business Regulatory Enforcement Fairness Act of 1996, both of which allow monies spent on corrective actions to be deducted from the fine imposed. CMP action, therefore, can provide noncompliant firms with a financial incentive to come into compliance.

The final CMP rule governing the procedures to be used in CMP matters was published in the **Federal Register** of July 27, 1995 (60 FR 38612), and is codified at 21 CFR part 17.

This draft guidance represents the agency's current thinking on the use of CMP recommendations made under the SMDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. This draft guidance is issued as a Level 1 draft guidance consistent with good guidance practices.

II. Electronic Access

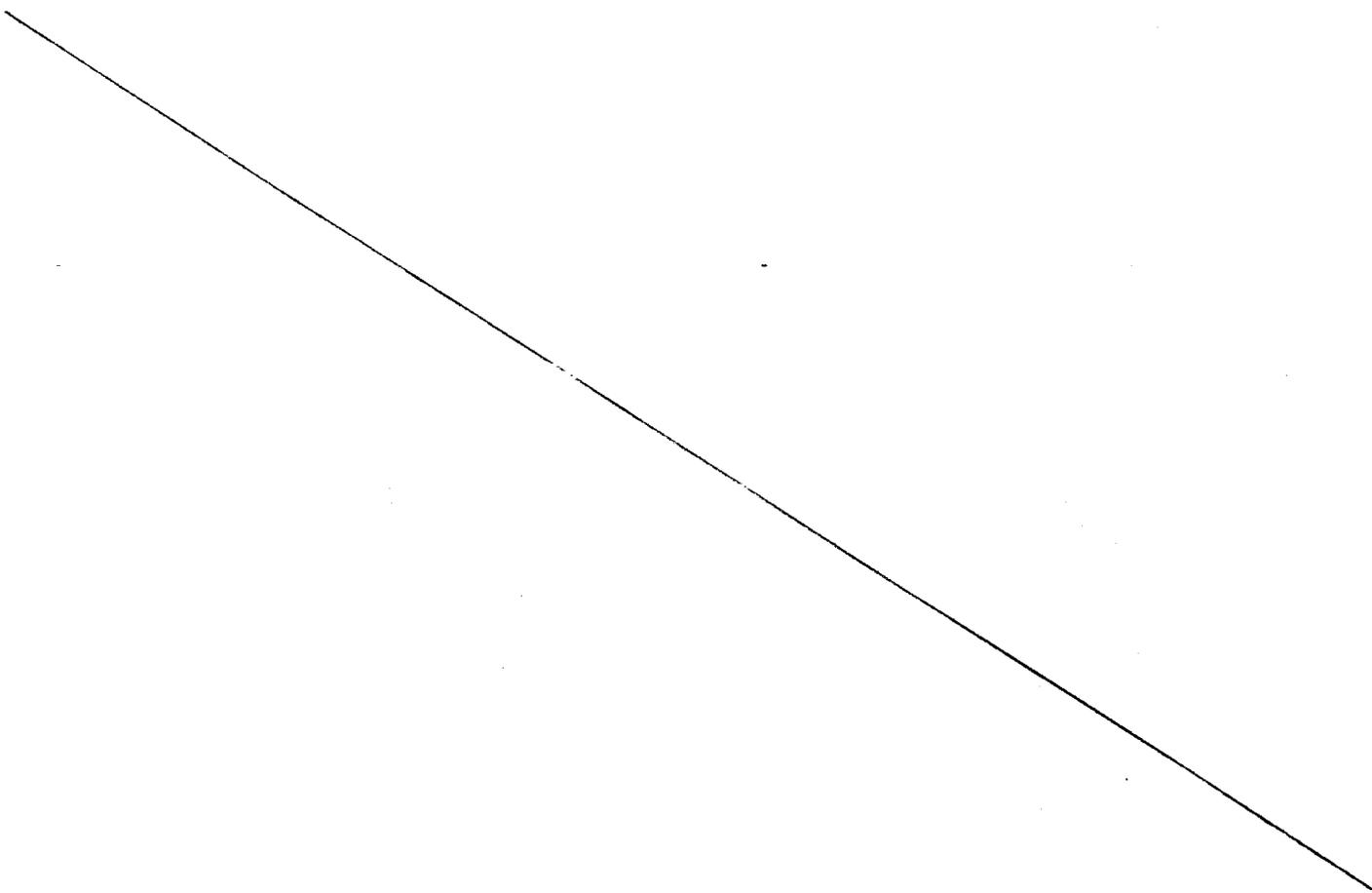
In order to receive "Guidance for FDA Staff on Civil Money Penalty Policy" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1124) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry

on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at "<http://www.fda.gov/cdrh>". "Guidance for FDA Staff on Civil Money Penalty Policy" will be available at "<http://www.fda.gov/cdrh/oc>".

III. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found



in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/25/99
May 25, 1999

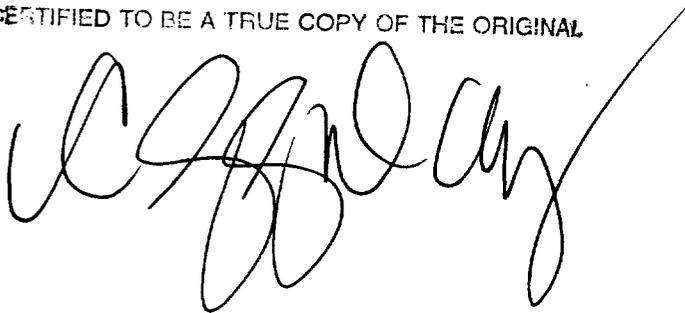
Linda S. Kahan

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

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CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

A large, stylized handwritten signature in black ink, appearing to read "Linda S. Kahan".