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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier G. Purley

Medical Device Warning Letter Pilot Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Medical Device Warning Letter Pilot (MDWLP). This pilot concerns the issuance of warning letters for quality system, premarket notification (510(k)), and labeling violations. The intent is to inform the medical device industry of FDA's decision to discontinue this pilot program.

DATES: The effective date for ending the MDWLP is *[insert date 30 days after date of publication in the Federal Register]* for inspections or investigations initiated on or after that date.

FOR FURTHER INFORMATION CONTACT: Jeffrey B. Governale, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0411, FAX 301-827-0482.

SUPPLEMENTARY INFORMATION:

I. Background

During the FDA and medical device industry grassroots forums, several issues were discussed concerning the agency's interaction with the device industry. After considering these issues, the agency initiated the MDWLP on March 29, 1999. (See the **Federal Register** of March 8, 1999 (64 FR 11018),

for a copy of the pilot.) The purpose of this pilot was to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. The MDWLP included procedures for the issuance of warning letters for quality system (21 CFR part 820), 510(k) (21 CFR part 807, subpart E), and labeling (e.g., 21 CFR part 800, subpart B; part 801; and part 809, subparts B and C) violations. This pilot was restricted to the medical device industry and was one of several medical device industry initiatives. FDA continued this pilot after the scheduled termination date of September 8, 2000, while evaluating its effectiveness.

After evaluating its effectiveness, FDA has decided to discontinue the pilot. The pilot was intended to optimize resource utilization, enhance communication between the medical device industry and FDA, and provide firms with incentives to promptly correct violations or deficiencies. However, FDA has determined that the pilot has not provided incentives to promptly correct violations because firms that would have received warning letters if not for the pilot, did not have measurably better rates of compliance in followup inspections than did firms that received warning letters. Also, FDA found that the pilot did not optimize resource utilization in that while the quantity of timely responses to inspectional observations increased, the quality of those responses generally decreased. Thus, FDA determined that the additional burdens placed on field staff by the pilot failed to optimize resources and reduced overall field inspectional effectiveness.

Additionally, on November 29, 2001, the Department of Health and Human Services directed FDA to submit all warning letters and untitled letters to FDA's Office of the Chief Counsel prior to their issuance for review of legal

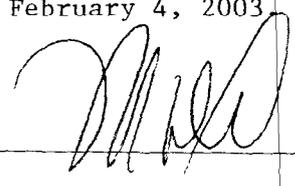
sufficiency and consistency with agency policy. FDA's new procedures for review of warning and untitled letters address some of the concerns that the medical device industry originally expressed to FDA during the grassroots meetings. The procedures have the added benefit of applicability to all FDA programs. They are expected to enhance consistency with agency policy among FDA district offices and centers, improve the legal sufficiency and quality of enforcement correspondence, and provide for timely feedback to regulated entities.

For all of these reasons, the agency has decided to discontinue the MDWLP.

II. Electronic Access

A copy of the MDWLP may be downloaded to a personal computer with access to the Internet at <http://www.fda.gov/ohrms/dockets/98fr/030899e.pdf>.

Dated: 2/4/03
February 4, 2003



Margaret M. Dotzel,
Assistant Commissioner for Policy.

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