

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0331]

DMB

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**Medical Devices; Implementation of Third Party Programs Under the FDA
Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties;
Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revision to the guidance document entitled "Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997." The revised guidance supersedes the October 30, 1998, guidance. FDA has amended the October 30, 1998, guidance to include criteria for the review of additional moderate risk (class II) devices by accredited persons under the Federal Food, Drug, and Cosmetic Act (the act). The revised guidance will assist those who are interested in participating in the expanded program, which is now in effect.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties" 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. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified
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NAD 2

with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Center for Devices and Radiological Health (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-6597.

SUPPLEMENTARY INFORMATION:

I. Background

On August 1, 1996, FDA began a voluntary Third Party Review Pilot Program for selected medical device premarket notifications ("510(k)'s"). The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices an alternative 510(k) review process that could yield more rapid marketing clearance decisions; and (2) enable FDA to target its scientific review resources at higher risk devices, while maintaining confidence in the review by third parties of low-to-moderate risk devices. Under the program, all class I devices that were not exempt from 510(k) at that time and 30 class II devices were eligible for third party review.

The Food and Drug Administration Modernization Act of 1997 (FDAMA) was signed into law by former President Clinton on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the Third Party Review Pilot Program by establishing section 523 of the act (21 U.S.C. 360m). Section 523 of the act directs FDA to accredit third parties (accredited persons) in the private sector to conduct the initial review of 510(k)'s for low-to-moderate risk devices and make recommendations to FDA regarding the initial classification of these devices under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). FDA published criteria in the **Federal Register** of May 22, 1998 (63 FR 28388), to grant or deny accreditation to persons who request to review 510(k)'s. In addition, FDA issued a list of devices that were eligible for review by accredited persons (May 20, 1998), which was updated in June 2000 to include additional class II devices for which device-specific guidance exists. This list is available on the Internet at <http://www.fda.gov/cdrh/thirdparty>. FDA also issued a guidance document entitled "Guidance for Staff,

Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997” (October 30, 1998). On November 21, 1998, FDA began accepting reviews and recommendations from accredited persons. Concurrently, FDA terminated the Third Party Review Pilot Program that began on August 1, 1996.

Industry use of third parties has been low. In an effort to encourage greater use of the Accredited Persons Program, the agency announced in the **Federal Register** of July 18, 2000 (65 FR 44540), a proposal to initiate a pilot that would allow third parties to review a significantly greater number of devices (hereinafter referred to as the July 2000 notice). Accordingly, FDA issued a draft revision of the October 30, 1998, guidance document and made available a proposed list of additional devices that would be eligible under the pilot.

The pilot would expand the device list by allowing, subject to certain specified conditions, third party review of class II devices for which device-specific guidance does not exist. Until now, device-specific guidance has existed for each class II device that is eligible for third party review. The pilot program would also include devices for which there is an exemption from 510(k). That is, if a new version of an exempted device requires a 510(k) because it exceeds the limitations of the 510(k) exemption for that device (as described in FDA’s device classification regulations), the device would be eligible for third party review. The pilot, together with the existing device list, would allow third party review of all class I and class II devices regulated by CDRH that the agency believes are not prohibited from such review under the statute. Section 523(a)(3)(A) of the act specifies that an accredited person may not review: (1) A class III device, (2) a class II device which is intended to be permanently implanted or life-supporting or life-sustaining, or (3) a class II device which requires clinical data in the report submitted under section 510(k). (Section 523 of the act sets limits on the number of class II devices that may be ineligible for accredited person review because clinical data are required.)

As with the current Accredited Persons Program, the pilot would not include 510(k)’s that require multi-Center review (e.g., 510(k)’s for drug/device combination products) or devices for

which the Center for Biologics Evaluation and Research has primary responsibility for review. FDA believes that the expanded number of devices resulting from the pilot and the existing program will be sufficient to satisfy the criteria in section 523(c) of the act that trigger a 4- or 5-year timeframe for the duration of the Accredited Persons Program.

Both the draft revised guidance document and the July 2000 notice provided an opportunity for public comment, which closed September 1, 2000. Based on the comments received, the following substantive changes have been incorporated into the final version of the revised guidance.

1. Section II.B (Outline of the Accredited Persons Review Program—Purpose and Nature of the Program) has been revised as follows:

- FDA has clarified that accredited persons should receive expanded accreditation in order to review devices in the pilot.
- The recommended conditions for participation in the pilot have been revised. The condition that an accredited person complete three successful 510(k) reviews under the third party program in order to participate in the pilot has been retained. However, the condition that at least one of the reviews be in the same or a similar medical specialty area as the pilot devices that the accredited person intends to review has been removed. Also, the condition that an accredited person contact the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a review of a device under the pilot has been revised. The revised condition for prereview contact applies only if the accredited person has not previously reviewed this type of device, i.e., a prereview contact is expected for the accredited person's first review of a particular device type but not for subsequent reviews of the same device type.
- The stated purpose of the prereview contacts has been revised for consistency with the above changes. Also, FDA has clarified that an accredited person's summary of prereview contacts: (1) Should be submitted to ODE with the accredited person's 510(k) review, (2) does not require prior ODE review or concurrence, and (3) is intended to be a simple record of the contacts rather than an "agreement" or de facto guidance.

2. Section II.B (Outline of the Accredited Persons Review Program—Devices Eligible for Accredited Person Review) has been revised to state that FDA will monitor the pilot continuously and will conduct a review 24 months, rather than 12 months, after it begins.

3. Section II.B (Outline of the Accredited Persons Review Program—Identification of an Accredited Person) has been revised to remove language encouraging manufacturers to use multiple accredited persons. In this context, the language was interpreted as suggesting that manufacturers should not interact repeatedly with the same accredited person, which was not FDA's intent.

FDA believes that the revised guidance will contribute to timely and consistent third party reviews of 510(k)'s for the expanded list of devices. Accredited persons who wish to expand their accreditation to include devices in the pilot should submit a request to FDA, as described in Section III of the revised guidance document.

II. Significance of Guidance

This guidance represents the agency's current thinking on expanding the scope of the Accredited Persons Program to include all devices not excluded by statute. 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.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (65 FR 56468, September 19, 2000). This guidance document is issued as a Level 1 guidance consistent with FDA's GGP's regulation.

III. Electronic Access

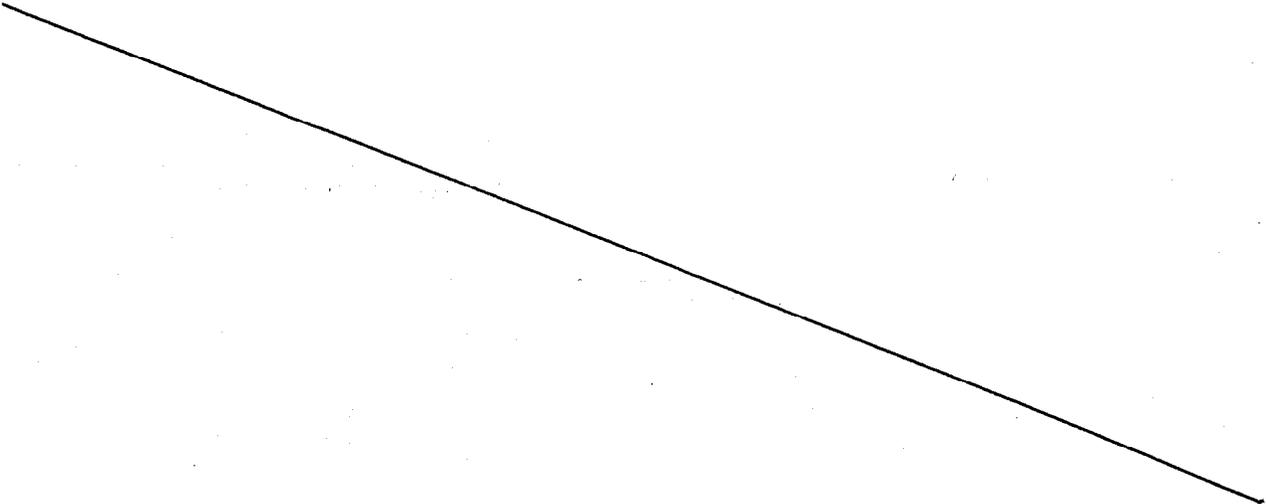
In order to receive "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties" via your fax machine, call CDRH Facts-on-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone

telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1160) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. 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> "Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties" is available at <http://www.fda.gov/cdrh/thirdparty>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the guidance at any time. Such comments will be considered when determining whether to amend the current 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 guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 2/26/01
February 26, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director for Regulations
Policy, Center for Devices and Radiological Health.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

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