

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0331]

Medical Devices; Draft Guidance for Staff, Industry, and Third Parties Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of Availability.

DMB

Display Date	<i>7-17-00</i>
Publication Date	<i>7-18-00</i>
Certifier	<i>S. K. Reese</i>

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revision to the guidance entitled, "Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997." FDA is proposing to amend this guidance to provide procedures for third party review of additional moderate risk (class II) devices under the FDA Modernization Act of 1997 (FDAMA) Accredited Persons Program. As described in this document and in the draft guidance, FDA intends to expand the list of devices eligible for third party review. The revised guidance would assist those who are interested in participating in the expanded program.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in the preparation of the final document by *[insert date 45 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" to the Division of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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

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 with the docket number found in brackets in the heading of this document.

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. The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices an alternative 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 premarket notification (510(k)) at that time and 30 class II devices were eligible for third party review. During the first 18 months of the pilot program, FDA received 22 510(k)'s that were reviewed by Recognized Third Parties. In contrast, during the same period, FDA received more than 1,300 510(k)'s for third party eligible devices that were not reviewed by third parties.

FDAMA was signed into law by the President on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the Third Party Review Pilot Program by establishing a new section 523 of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 360m). Section 210 of FDAMA directs FDA to accredit third parties (Accredited Persons) in the private sector to conduct the review of 510(k)'s for low-to-moderate risk devices and make recommendations to FDA regarding the initial classification under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)).

FDA established and published criteria in the **Federal Register** on May 22, 1998 (63 FR 28388) to accredit or deny accreditation to persons who request to review 510(k)'s. In addition, FDA issued a list of devices that are eligible for review by Accredited Persons (May 20, 1998) as well as 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). Copies of these documents can be found at <http://www.fda.gov/cdrh/thirdparty>. By November 21, 1998, FDA accredited 13 organizations to review 510(k)'s, and the agency was prepared to begin accepting reviews and recommendations from Accredited Persons. Concurrently, FDA terminated the Third Party Review Pilot Program that began on August 1, 1996. In the first 17 months that the FDAMA third party program has been in effect, 28 companies have used third parties to review a total of 54 510(k) submissions. During that same period, nearly 2,000 510(k) submissions from approximately 800 companies were eligible for third party review. This approach has typically yielded rapid marketing clearance decisions. In fiscal year 1999, the average total elapsed time between a third party's receipt of a 510(k) submission and FDA's substantial equivalence determination was 57 days. The portion of this time that occurred between FDA's receipt of the third party's recommendation and FDA's determination averaged just 15 days. In spite of these advantages, industry use of the third party approach has been low.

In an effort to expand the use of the Accredited Persons Program, the agency is proposing to initiate a pilot that will allow third party review of a greatly expanded list of devices (see details below). Accordingly, FDA is issuing a draft revision of the guidance document entitled "Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" as well as making available an expanded list of additional devices that will be eligible under the pilot. Copies of these documents can be found at <http://www.fda.gov/cdrh/thirdparty>. After FDA reviews comments and finalizes this guidance, it will supersede the October 30, 1998, guidance currently in effect.

The May 20, 1998, list of devices eligible for review by Accredited Persons included 50 class I devices and 104 class II devices. FDA included all class I devices, not exempt from 510(k), because the agency determined that general guidance provided by CDRH is a sufficient basis for third party review of these relatively low risk products. However, FDA's decision to include class II devices was partly dependent on the existence of device specific guidance and/or FDA recognized standards. FDA is currently updating the May 20, 1998, list to reflect changes in device classification and to include additional Class II devices for which device specific guidance is now available.

In addition to updating the May 20, 1998, list, the agency is now proposing to initiate a pilot that will expand the device list by allowing third party review of all class II devices regulated by the Center for Devices and Radiological Health (CDRH) that the agency believes are not prohibited from such review under the statute¹, regardless of whether device specific guidance is available for the device. The pilot program will also include devices for which there is a limited exemption from 510(k). If a new version of a device requires a 510(k) because the change exceeds the limitation, that device is eligible for third party review unless it can not be reviewed by a third party because of the statutory exclusions under section 523 of the act. As with the current Accredited Persons Program, the expansion pilot will not include 510(k)'s that require multi-Center review (e.g., 510(k)'s for drug/device combination products) and devices for which the Center for Biologics Evaluation and Research has primary responsibility for review.

Any 510(k) for a class II device for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to initial and supervisory review by FDA

¹ Section 523(a)(3)(A) of the act specifies that an Accredited Person may not review: (a) A class III device; (b) a class II device which is intended to be permanently implanted or life-supporting or life-sustaining; or (c) 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.)

and will not be processed by FDA under the special procedures for the Accredited Persons Program. The decision to require clinical data is a matter of judgment that is often dependent on the nature of any differences between the new device and the device to which it is being compared (e.g., an additional specific indication for use). Manufacturers and Accredited Persons seeking guidance on the need for clinical data in a 510(k) should consult FDA's guidance documents and may also contact the appropriate review division in CDRH's Office of Device Evaluation.

FDA expects the pilot program to encourage more widespread use of the third party program. Under the pilot program, FDA will accept reviews from Accredited Persons of devices for which there is no device specific guidance under the following circumstances. An Accredited Person may review a class II device that does not have device specific guidance if:

(1) The Accredited Person has previously completed three successful 510(k) reviews under the third party program. This should include at least one 510(k) review that was in the same or similar medical specialty area as the device the Accredited Person now intends to review. The prior 510(k) reviews can be for class II devices that have device specific guidance or for class I devices.

(2) The Accredited Person contacts the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) before initiating a 510(k) review for a class II device that does not have device specific guidance to confirm that the Accredited Person meets the criteria in paragraph 1 above and to identify pertinent issues and review criteria related to this type of device.

(3) The Accredited Person prepares a summary documenting the discussions and submits the summary of those discussions to ODE.

The discussion and summary would not be binding on the agency or the Accredited Person. The presubmission discussions and the creation of a record of those discussions will help FDA ensure the consistency and timeliness that can be provided by device specific guidances. In addition, the FDA may utilize such documentation to ensure consistency in its own interactions with different Accredited Persons and regular submitters. Moreover, the record of these discussions will help

FDA determine whether there is a need to issue device specific guidance and could facilitate future development of those documents.

The pilot will begin after FDA reviews comments and finalizes the guidance entitled “Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs under the FDA Modernization Act of 1997.” Existing Accredited Persons should refer to the guidance for procedures on how to expand the scope of their accreditation. In addition, persons seeking to become accredited under section 523 of the act also should refer to the procedures in this guidance.

The agency intends to review the pilot program in 12 months after it begins to see if the number of third party 510(k)'s has increased significantly, if the timeliness of review is maintained, and to consider whether particular divisions within CDRH's Office of Device Evaluation are devoting disproportionate staff time to presubmission discussions with Accredited Persons. The agency reserves the option to stop or reevaluate the pilot at any time it determines that additional work load generated by third party consultations compromises FDA's ability to review other applications or the agency has reason to believe the quality of the reviews is significantly diminished by lack of device specific guidance.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on expanding the scope of the Accredited Persons Program to include class II devices not excluded by statute. It does not create nor 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 (62 FR 8961, February 27, 1997). This guidance document is issued as a draft Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive “Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997,” 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 draft 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>. “Guidance for Staff, Industry and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997” will be available at <http://www.gov/cdrh/dsma/3rdptythirdparty>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance by [*insert date 45 days after date of publication in the Federal Register*]. 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. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/5/00
July 5, 2000

Linda S. Kahan

Linda S. Kahan,
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