

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

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This document supersedes the document entitled "Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997" dated October 30, 1998.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

**Office of In Vitro Diagnostics and Radiological
Programs**

Preface

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact CDRH Third Party Premarket Review Program by email at CDRHThirdPartyPremarketReviewProgram@fda.hhs.gov.

Additional Copies:

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1160) to identify the guidance you are requesting.

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

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. What is the Purpose of this Guidance?

This guidance is for those who are interested in the Food and Drug Administration's (FDA's) third party review program including:

- Persons accredited to perform premarket notification [510(k)] reviews (Accredited Persons),
- 510(k) applicants, and
- FDA staff responsible for implementing the program.

II. Introduction

A. What is the History of Third Party Review for Medical Device Submissions?

Purpose of Section 510(k)

The current regulatory framework for medical devices was created by the Medical Device Amendments of 1976 (the amendments) to the act, as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the FDA Modernization Act of 1997 (FDAMA). Section 513(a) of the act [21 U.S.C. 360c(a)] establishes three device classes and directed FDA to publish regulations classifying each device on the market into one of those three classes.

Classification is based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of a device.

1. Class I devices (general controls). General controls include (among others):
 - establishment registration,
 - device listing,
 - premarket notification,
 - records and reports, and
 - current good manufacturing practices requirements.

General controls apply to all three classes of devices.

2. Class II devices (special controls). Special controls include:
 - promulgation of performance standards,
 - postmarket surveillance,
 - patient registries,
 - dissemination of guidelines and recommendations
 - other appropriate actions FDA deems necessary to provide reasonable assurance of the safety and effectiveness of the device.
3. Class III devices (premarket approval). A preamendments class III device is not required to receive premarket approval until the effective date of a regulation calling for premarket approval promulgated under section 515(b)(2) of the act.

Under sections 510(k) and 513(f) of the act, a manufacturer of a new device may receive marketing clearance for the device by submitting a premarket notification to FDA demonstrating that the device is substantially equivalent to a legally marketed device that does not require premarket approval. If FDA finds the device is not substantially equivalent to a legally marketed device, the manufacturer must obtain premarket approval of the device or have the device reclassified into class I or class II before marketing the device.

Section 513(i) of the act defines the term "substantially equivalent." Substantial equivalence means that a device:

- (1) has the same intended use and the same technological characteristics as a legally marketed device; or
- (2) has the same intended use and different technological characteristics, but there is information in the 510(k) demonstrating that the device is as safe and effective as a predicate device, and the device does not raise different questions of safety and effectiveness.

Scientific review staff within CDRH make substantial equivalence determinations based primarily upon information provided in a manufacturer's 510(k).

FDA has published regulations (21 CFR part 807, subpart E) specifying 510(k) content and procedures. FDA also has developed numerous guidance documents and policy memoranda for the 510(k) program. These are available on the Center for Devices and Radiological Health (CDRH) Home Page at <http://www.fda.gov/cdrh>, or from the Division of Small Manufacturers Assistance (DSMA), as discussed later in this document.

Third Party Review Pilot Program

On August 1, 1996, FDA began a voluntary Third Party Review Pilot Program for selected medical device 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 use its scientific review resources for 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.

FDAMA

The President signed FDAMA into law on November 21, 1997. Section 210 of FDAMA essentially codified and expanded the pilot program by establishing section 523 of the act, which:

- (1) 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
- (2) specifies that an Accredited Person may not review any class III device, or class II devices that are permanently implantable, life-supporting, life-sustaining, or for which clinical data are required
- (3) sets limits on the number of class II devices that may be ineligible for Accredited Person review because clinical data are required.

On September 23, 1998, FDA published a list of persons accredited to conduct 510(k) reviews for certain devices, which is available at <http://www.fda.gov/cdrh/thirdparty>. Accredited Persons were eligible to begin to review applications after they successfully completed a training session. On November 21, 1998, the agency began accepting 510(k) reviews from Accredited Persons, and terminated the Third Party Review Pilot Program that began on August 1, 1996.

In accordance with FDAMA, FDA established criteria to grant or deny accreditation to persons who:

1. request to review reports submitted under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act), and

2. make recommendations to FDA regarding the initial classification of devices under section 513(f)(1) of the act.

FDA published these criteria in the FEDERAL REGISTER on May 22, 1998 (63 FR 28388). In addition, FDA issued a guidance document on October 30, 1998 for staff, industry, and third parties on implementation of the third party program. This current document is a revision of the October 30, 1998 guidance. FDA is issuing this revised guidance to include criteria for the review of additional moderate risk (class II) devices.

In the past, FDA's policy permitted third party review of class II devices only if device-specific guidance or recognized consensus standards existed. The agency instituted this policy to ensure that there would be consistency among different third party reviewers and to enhance the timeliness of the agency's review process once a third party submits a recommendation. FDA believes the extremely short time frames that have been associated with third party reviews are, in part, attributable to this policy. However, in an effort to expand use of the third party program, the agency is initiating a pilot that will allow third party review of any device regulated by CDRH that is not prohibited from such review under the statute. This guidance includes information on this pilot. We expect the pilot to last for two years and will evaluate the outcome at the end of that period.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed by participants in this program. In developing the guidance, we carefully considered the relevant statutory criteria. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, please contact us. You may send your comments to the contact person listed in the preface to this guidance. Also, comprehensive information on dispute resolution at CDRH is listed on the CDRH Ombudsman's web page: <http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html>.

B. What is the Accredited Persons Review Program?

Purpose and Nature of Program

The purpose of the Accredited Persons Program is to implement section 523 of the act by accrediting third parties to conduct the initial review of 510(k)s for selected low-to-moderate risk devices.

The Accredited Persons Program is intended to enable FDA to use its scientific review resources for higher-risk devices, while maintaining a high degree of confidence in the review of low-to-moderate risk devices by Accredited Persons, and to provide manufacturers of eligible devices an alternative review process that may yield more rapid 510(k) decisions.

In accordance with the requirements of section 523, and based on experience with the Third Party Review Pilot Program, FDA's initial implementation of the Accredited Person Program included a number of features designed to maintain a high level of quality in 510(k)s reviewed by Accredited Persons and to minimize risks to the public.

These included:

- Exclusion of all class III devices and any class II devices that are permanent implants, life-supporting/life-sustaining, or which require clinical data (the act limits the number of class II devices that may be ineligible for Accredited Person review because of the need for clinical data);
- FDA assessment, accreditation, and training of Accredited Persons before their participation in the program;
- Personnel qualifications for Accredited Persons equivalent to the level within the CDRH's Office of Device Evaluation;
- Criteria to prevent potential conflicts of interest for Accredited Persons that might affect the review process;
- FDA oversight of Accredited Person reviews/recommendations and FDA's continued responsibility for the issuance of 510(k) decisions;
- Provisions for FDA to make onsite visits on a periodic basis to each Accredited Person to audit performance and to inspect records, correspondence, and other materials relating to Accredited Person review;
- FDA monitoring and evaluation of the program to ensure that Accredited Persons are substantially in compliance with the requirements of section 523 and that they do not pose a threat to public health;
- Continued applicability of all other regulatory controls (e.g., medical device reporting of post-marketing adverse events) applicable to devices included in the program;
- Prohibition against forum shopping by submitters of 510(k)s; and
- Reliance by Accredited Persons on review guidance and/or recognized standards to ensure consistent and timely review.

FDA is now initiating a pilot program to encourage more widespread use of the Accredited Persons Program. Subject to the conditions specified below, the pilot allows Accredited Persons to review 510(k)s for class II devices for which device-specific guidance does not exist. An Accredited Person should request expanded accreditation in order to review these devices (see Section IV of this guidance document). An Accredited Person may receive accreditation to review class II devices that do not have device-specific guidance if the following conditions are met or the Accredited Person can establish that it has the appropriate expertise to review the devices it wishes to review:

- 1) The Accredited Person has previously completed three successful 510(k) reviews under the third party program. The prior 510(k) reviews may be for class II devices that have device-specific guidance or for class I devices.
- 2) The Accredited Person agrees to contact the appropriate CDRH Office of Device Evaluation (ODE) Branch Chief (or designee) when initiating a 510(k) review for a type of device in the pilot that the Accredited Person has not previously reviewed. The purpose of the contact is to identify pertinent issues and review criteria related to this type of device. Following the discussion with the Branch Chief, the Accredited Person may conduct the review. The Accredited Person may conduct subsequent reviews of 510(k)s for the same type of device without a pre-review contact.
- 3) The Accredited Person agrees to prepare a summary documenting the discussion and to submit the summary to ODE with its 510(k) review, as specified in Section II, Review Materials to be Submitted to FDA by an Accredited Person. The summary does not need prior review or concurrence by ODE.

The discussion and summary do not constitute an agreement and are not binding on the agency or the Accredited Person. Rather, the pre-submission discussions and the creation of a record of those discussions will help FDA ensure the consistency and timeliness of reviews in the absence of 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 a particular device-specific guidance and might facilitate the development of such a document.

FDA provides information on procedures and criteria that it uses for 510(k) reviews in general guidance and in a training program that was originally conducted by FDA before commencement of the third party program. This training program is repeated as needed. Accredited Persons may access the CDRH Home Page for general information on regulatory guidance and on FDAMA at <http://www.fda.gov/cdrh>. At this website Accredited Persons may also consult existing FDA guidance documents, such as

- "Premarket Notification 510(k) - Regulatory Requirements for Medical Devices" (August 1995),
- "In Vitro Diagnostic Devices: Guidance for the Preparation of 510(k) Submissions" (January 1997),
- "Third Party Review – An Instruction Manual for Conducting Reviews of Premarket Notifications" (July 1, 1996),
- "Guidance on the Recognition and Use of Consensus Standards" (February 1998),
- "Guidance on the Use of Standards in Substantial Equivalence Determinations" (March 2000), and

- "Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff" (January 1998).

These publications provide an overview of device regulations, FDA requirements concerning 510(k) content and format, a description of the 510(k) review process, important policy memoranda, and additional information useful to manufacturers and Accredited Persons (see Section V).

FDA encourages Accredited Persons and those seeking accreditation to be familiar with the information outlined in these publications and in subsequent guidance. This information, any device-specific review guidance made available by FDA, and pre-submission discussions will assist the Accredited Persons in producing adequate reviews that the agency can process in a timely manner.

Which Devices Are Eligible for Accredited Person Review?

As noted above, section 523 of the act limits the types of devices that Accredited Persons may review. FDA has made available on the CDRH Home Page a list of class I and class II devices regulated by CDRH that the agency believes are not prohibited from Accredited Person review under the act. This list of devices is available at <http://www.fda.gov/cdrh/thirdparty>, and will be updated periodically.

Previously, FDA's list of devices eligible for review by Accredited Persons was more limited. The list included all class I devices not exempt from premarket notification, because the agency determined that general guidance provided by CDRH is a sufficient basis to assist third party review of these relatively low-risk devices. The decision to include class II devices was, however, partly dependent on the existence of device-specific guidance and/or FDA recognized standards.

In an effort to encourage greater use of the Accredited Persons Program, FDA is initiating a pilot, discussed earlier in this document, that expands the list of eligible devices to include class II devices for which device-specific guidance does not exist. Devices that are eligible under the pilot are included in the agency's CDRH Home Page list of eligible devices and are identified as "pilot" devices to distinguish them from devices that may be reviewed without regard to the special pilot program procedures. The pilot also includes devices that are exempt 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 (as described in FDA's device classification regulations), that device would be eligible for third party review unless it cannot be reviewed by a third party because of the statutory exclusions under section 523 of the act. While these "exempt" devices are not shown on the list of eligible devices, the introduction to the list notifies manufacturers and Accredited Persons that, subject to the statutory limitations, FDA will accept third party reviews for devices that require a 510(k) submission because they exceed the limitations of the 510(k) exemption for that device.

As with the existing Accredited Persons Program, the pilot does 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. Also, subject to the limitations of the law, any 510(k) for a class II device for which clinical data are needed to make a determination of substantial equivalence is not included in the Accredited Persons Program. The decision to require clinical data is a matter of professional 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.

The agency intends to monitor the pilot continuously and will review the pilot 24 months after it begins to see if the number of third party reviews of 510(k)s increases significantly, if the timeliness of review is maintained, and if particular divisions within CDRH's Office of Device Evaluation are spending more staff time than expected in pre-submission discussions with Accredited Persons. The agency reserves the option to stop or reevaluate the pilot at any time if it determines that additional workload generated by third party consultations compromises FDA's ability to review other applications or that the quality of the reviews is significantly reduced by lack of device-specific guidance.

How Do You Become an Accredited Person?

We (FDA) serve as the accreditor for third parties under section 523 of the act. Our accreditation criteria were published in the FEDERAL REGISTER on May 22, 1998, and we address this further in Section II B. of this document, Qualifications of Accredited Persons. There is no limit on the number of qualified persons who may become Accredited Persons. You may apply to be an Accredited Person for the review of a broad range of device types or to review specific types of devices. In all cases, we accredit only applicants with qualified personnel and stringent conflict of interest standards. In addition, we consider accreditation applications from both domestic and foreign persons. However, all applications and communications with the agency and all documentation pertaining to the review of a 510(k) should be in English and, for foreign Accredited Persons, made by a United States representative so that we may do an adequate review and efficiently communicate with applicants.

We maintain a list of Accredited Persons eligible to submit 510(k) reviews to us at <http://www.fda.gov/cdrh/thirdparty>. This list provides the name, contact person, address and telephone number of the Accredited Person. We update the list routinely. You should promptly notify FDA of any changes in this information.

When May We Withdraw Your Accreditation?

In accordance with section 523(b)(2), we may suspend or withdraw your accreditation, after providing you notice and an opportunity for an informal hearing, when you:

- 1) are not substantially in compliance with section 523;
- 2) fail to act in a manner consistent with the purposes of section 523; or
- 3) pose a threat to public health.

In addition, it is a prohibited act under section 301(y)(1) for you, as an Accredited Person, to:

- 1) submit a report that is false or misleading;
- 2) disclose confidential information or trade secrets without the submitter's consent; or
- 3) receive bribes or perform a corrupt act.

Consistent with current practice, we will continue to accept 510(k)s from third parties that have not been accredited, but will treat the submission in the same manner as a 510(k) submitted directly from a manufacturer.

If you wish to become accredited, you should submit an application to us addressed to: Accredited Person Program, Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 1350 Piccard Drive, Rockville, Maryland 20850 USA. You should use the format for accreditation applications described in Section III. We will make a decision to accredit or not to accredit within 60 days of receiving your application.

What Qualifications Are Necessary to Become an Accredited Person?

To be accredited by us, you must demonstrate that you have the appropriate qualifications and facilities to conduct competent 510(k) reviews and that you have instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

In accordance with section 523(b)(3), to be accredited by us, you must, at a minimum, have the following qualifications:

- 1) You may not be a Federal Government employee;
- 2) You must be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of devices and have no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor;
- 3) You must be a legally constituted entity permitted to conduct the activities for which you seek accreditation;
- 4) You must not engage in the design, manufacture, promotion, or sale of devices;
- 5) You must operate in accordance with generally accepted professional and ethical business practices and agree in writing that as a **minimum** you will:
 - (i) certify that reported information accurately reflects data reviewed;

- (ii) limit work to that for which competence and capacity are available;
- (iii) treat information received, records, reports, and recommendations as proprietary information;
- (iv) promptly respond and attempt to resolve complaints regarding activities for which you are accredited; and
- (v) protect against the use of any officers or employees to conduct reviews when that person has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the Accredited Person, officers and employees have maintained compliance with requirements relating to financial conflicts of interest.

In addition to the minimum requirements for Accredited Persons set forth in the act, you should have the following qualifications (see 63 FR 28388, May 22, 1998):

1) Personnel.

We will consider several factors with respect to personnel qualifications when accrediting applicants. These include:

- a) whether personnel have demonstrated knowledge of:
 - the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);
 - the Public Health Service Act (42 U.S.C. 201 et seq.); and
 - regulations implementing these statutes, particularly 21 CFR parts 800-1299.
- b) whether the applicant:
 - has established, documented, and executed policies and procedures to ensure that 510(k)s are reviewed by qualified personnel, and whether it will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k);
 - has clear, written instructions for duties and responsibilities with respect to 510(k) reviews available to its personnel;
 - has employed personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)s that the Accredited Person accepts for review;
 - has identified at least one individual who is responsible for providing supervision over 510(k) reviews and who has

sufficient authority and competence to assess the quality and acceptability of these reviews; and

- is prepared to conduct technically competent reviews at the time of requesting accreditation by FDA.
- c) for appropriate review of a particular class II device, we will expect specialized education or experience to assure a technically competent review.

Information on the general education and experience that we require of our scientific review personnel is included in the appendix, Qualification Standards for FDA Reviewers. You may use these criteria to ensure that your personnel with primary responsibility for review of 510(k)s have appropriate education and experience. You may develop and apply alternative criteria that result in personnel with appropriate education and experience necessary to review 510(k)s.

2) Facilities.

Accredited persons should have the capability to interface with FDA's electronic data systems, including the FDA Home Page, CDRH Home Page, and the CDRH Facts-On-Demand system. At a minimum, this would include a computer system with a modem and an independent facsimile machine. We will rely extensively on the use of our electronic data systems for timely dissemination of guidance documents to Accredited Persons and other interested parties (see [Section V](#)).

3) Prevention of Conflicts of Interest.

We expect you as an Accredited Person to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of conflict of interest. To that end, when deciding whether to accredit a person, we will consider whether you have established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest, including conflicts of contractors or individual contract employees.

Although it is not feasible to identify all of the circumstances that would raise concerns about conflicts of interest, the most common conditions that might indicate a potential conflict of interest are:

- (a) the Accredited Person is owned, operated, or controlled by a device manufacturer or distributor;
- (b) the Accredited Person has any ownership or financial interest in any medical device, device manufacturer, or distributor;
- (c) any personnel of the Accredited Person involved in 510(k) reviews has an ownership or other financial interest in a device manufacturer or distributor that presents the appearance of a conflict of interest;
- (d) any personnel of the Accredited Person is involved in the 510(k) review of any device in which he or she has any ownership or financial interest;
- (e) the Accredited Person or any of its personnel involved in 510(k) reviews participates in the design, manufacture, or distribution of any medical device;
- (f) the Accredited Person or any of its personnel involved in 510(k) reviews provides consultative services to any device manufacturer or distributor regarding specific devices;
- (g) the Accredited Person or any of its personnel involved in 510(k) reviews participates in the preparation of 510(k)s;
- (h) in reviewing a 510(k) the Accredited Person uses personnel who were employed within the last twelve months by the firm who submitted the 510(k) for review; or
- (i) the fees charged or accepted are contingent or based upon the recommendation for initial classification made by the Accredited Person.

You may assess a fee for your services as an Accredited Person. You may also conduct other activities, such as objective laboratory testing of devices or assessment of conformance to standards, if those other activities do not affect the impartiality of 510(k) reviews. In addition, you may provide general information on 510(k) requirements to permit the submitter to improve the organization or content of a 510(k) that you are reviewing.

When you, as an Accredited Person, use the services of a contractor in connection with a 510(k) review, you are responsible for the contracted work of your contractor. You should assure that the

contractor meets the same criteria for freedom from conflicts of interest as an Accredited Person.

Information on the conflict of interest standards FDA applies to its own review personnel is included in the appendix, Standards for Ethical Conduct for Employees of the Executive Branch. You may adopt these standards as one means of safeguarding your operations against conflicts of interest.

4) Training.

In accordance with the criteria established by FDA in the FEDERAL REGISTER on May 22, 1998, Accredited Persons are to certify in their application that they will have designated employees attend FDA training for Accredited Persons. FDA conducted initial training for Accredited Persons on October 14-16, 1998 and plans to provide such training on a periodic basis for Accredited Persons.

You should complete training before conducting any 510(k) reviews under the program. FDA does not accept 510(k) reviews and recommendations from Accredited Persons that have failed to have at least one designated employee attend an FDA training session for Accredited Persons.

Identification of an Accredited Person

Submitters of 510(k)s interested in using an Accredited Person should access the CDRH Home Page for a list of Accredited Persons and the name and address of each Accredited Person's contact. Persons that do not appear on the list of Accredited Persons are not eligible to review 510(k)s under section 523 of the act.

If our monitoring of the program reveals that manufacturers are developing business relationships with Accredited Persons that call into question the independence or objectivity of the Accredited Person, we will consider implementing a process that limits the submitter's choice of Accredited Persons for a specific review. Business relationships that may undermine the independence or objectivity of an Accredited Person include contracts between a manufacturer and an Accredited Person that represent a significant share of the Accredited Person's income from all activities including the third party program over the period of the contract, such that continuation or termination of the contract may create the appearance of an undue financial influence.

We may refuse to process a 510(k) and consider the accompanying Accredited Person's review under section 523 if it appears to us that the submitter has engaged in "forum shopping" in order to find an Accredited Person who is most likely to recommend clearance of the submitter's 510(k). It is not feasible to identify or state categorically all

of the criteria for evaluating whether a submitter has “forum shopped.” However, if we determine that a submitter has obtained reviews of the same 510(k) from more than one Accredited Person, there will be a presumption of forum shopping and we may refuse to provide special processing of a submitter's 510(k) unless the submitter can explain to our satisfaction why the circumstances do not indicate forum shopping. If experience with the program indicates that submitters are engaging in such forum shopping, we will consider placing additional limits on and monitoring initial contacts between manufacturers and Accredited Persons.

Participation in the program is entirely voluntary. Submitters may continue to submit 510(k)s directly to FDA. Submitters may also hire or contract third parties other than those accredited by FDA, but only 510(k)s reviewed by Accredited Persons will be eligible for review within 30 days under section 523.

Review Materials to be Submitted to FDA by an Accredited Person

Upon completing review of a 510(k), you as an Accredited Person should submit the following documentation to FDA, in duplicate, in order to expedite timely agency review of your recommendation:

1. A cover letter signed by your contact person clearly identifying: the purpose of the submission; the name and address of the Accredited Person; the FAX and telephone number of the contact person; the name and address of the manufacturer/submitter; the name of the device (trade name, common or usual name, FDA classification name, classification regulation number, and product code); your recommendation with respect to the substantial equivalence of the device; and the date you first received the 510(k) from the manufacturer/submitter.
2. A letter signed by the manufacturer/submitter authorizing you to submit the 510(k) to FDA on its behalf and to discuss its contents with FDA.
3. A summary of any pre-submission discussion that occurred with the appropriate ODE Branch Chief or designee if this is your first review of this type of device under the expansion pilot, as discussed earlier in this guidance document.
4. The manufacturer's/submitter's complete 510(k) conforming to FDA's established requirements for content and format of such submissions.
5. A complete review of the 510(k), signed by all personnel who conducted the review and by an individual responsible for supervising 510(k) reviews, with a recommendation concerning the substantial equivalence of the device.

6. A certification that the reported information accurately reflects the data reviewed.
7. Any other information requested in FDA's information package for Accredited Persons.

We may not be able to process a 510(k) submitted by an Accredited Person if the review material discussed above is not included with the submission. If information necessary for the agency's review is not included, we will begin our review only after we receive the necessary information.

To ensure the integrity of the review process, you should submit all review materials and 510(k)s directly to FDA. You should submit this information to: CDRH Document Mail Center (HFZ-401), Attention: Accredited Person Reviews, 9200 Corporate Boulevard, Rockville, Maryland 20850 USA. If you submit any material in a foreign language, you should also include an English translation verified to be complete and accurate.

Document Processing by FDA

The CDRH Document Mail Center will route 510(k) submissions to the appropriate review division in CDRH's ODE. Premarket notifications [510(k)s] reviewed and submitted by Accredited Persons are expected to bypass the first phases of our usual review process, that is, the acceptance screening and initial scientific review, and instead be routed directly to the appropriate ODE supervisory official.

We expect the supervisory official to rely on the record of review prepared by you as an Accredited Person and to conduct a brief administrative assessment to determine whether your review is acceptable to us. We will apply the same criteria as for 510(k)s reviewed entirely within FDA. FDA intends to contact you if it has questions concerning the submission. The ODE supervisory official is expected to prepare our decision concerning the substantial equivalence of the device. We will send decision letters and other significant correspondence to your contact person, who should be responsible for communicating with the submitter of the 510(k).

If we disagree with the initial classification you recommend, we will provide a statement explaining the reasons to you, the Accredited Person, and to the person who submitted the 510(k). In section 523(a)(2) of the act, we are required to make a determination within 30 days following receipt of a 510(k) recommendation from an Accredited Person.

What Information Is Confidential?

Section 523(b)(3) of the act states that an Accredited Person is required to preserve and protect the confidentiality of all information it receives from a submitter.

FDA will determine the releasability of review information submitted to FDA by an Accredited Person in accordance with the agency's regulations implementing the Freedom of Information Act (21 CFR part 20) and 21 CFR §807.95, regarding confidentiality of information in 510(k)s. In general, 510(k) reviews submitted by Accredited Persons (like reviews conducted by FDA staff) will be available for disclosure by FDA after the agency has issued a substantial equivalence decision for a device, unless the information is exempt from public disclosure under part 20 or §807.95. If necessary, a copy of the 510(k) will be provided to the manufacturer for predisclosure notification according to §20.61.

In addition, information submitted by an Accredited Person to obtain approval for participation in the program will be available for disclosure by FDA, unless exempt under part 20.

What Records Should An Accredited Person Maintain?

Pursuant to section 704 of the act you must, at a minimum, maintain records that support your initial and continuing qualifications to be an Accredited Person. These records include:

- 1) documentation of the training and qualifications of the Accredited Person and the employees of the Accredited Person;
- 2) the procedures used by the Accredited Person for handling confidential information;
- 3) the compensation arrangements made by the Accredited Person; and
- 4) the procedures used by the Accredited Person to identify and avoid conflicts of interest.

In accordance with section 704 (f)(1), you must make these records available upon request to an officer or employee of FDA at all reasonable times and we may view, copy, or verify these records. Within 15 days of receiving a written request from us, you must make copies of any requested records available at a place we designate.

In addition, you should retain the following records for at least three years following submission of a review to FDA:

- 1) copies of the 510(k) reviews and associated correspondence;
- 2) information on the identity and qualifications of all personnel who contributed to the technical review of the 510(k); and
- 3) other relevant records.

What Fees May An Accredited Person Assess?

As an Accredited Person, you may assess a reasonable fee for your services. The fee for a 510(k) review is a matter to be determined by contract between the Accredited Person and the submitter, but we will consider the fee to present a conflict of interest if it is contingent or based on the type of recommendation made by the Accredited Person. The receipt of a bribe in any form is a prohibited act under 21 U.S.C. 331(y)(3).

III. What is the Format and Content of an Initial Accredited Person Application?

Persons wishing to become Accredited Persons under section 523 of the act should apply to the CDRH Third Party Review Board (TPRB). We are required to respond to your request for accreditation within 60 days of receiving your application.

We will fax a date-stamped acknowledgment letter to your contact person when we receive your application. The Third Party Review Board will review these materials and respond within 60 days of the date of the receipt of the application with either a letter of accreditation, a denial of accreditation, or a request for additional information. We may deny your request for accreditation if we determine that you do not meet the criteria established for Accredited Persons in the May 22, 1998, FEDERAL REGISTER Notice. We may deem incomplete and deny your request for accreditation if you fail to respond to a request for additional information in a timely manner. You may make a written request to the Director, Office of Health and Industry Programs (OHIP), CDRH, for reconsideration of a decision to deny your request for accreditation or to withdraw your accreditation.

You should include the following information in an application to demonstrate that you meet the qualifications addressed in Section II B, Qualifications of Accredited Persons.

A. Administrative Information

- 1) Name and address of the person seeking accreditation;
- 2) Telephone number and FAX number of the contact person. The contact person should be the person to whom questions about the content of the application may be addressed and the person to whom a letter of determination and general correspondence will be directed;

- 3) Name and title of the most responsible individual at the firm. Foreign applicants should also identify the name, address, telephone number, and FAX number of an authorized representative located within the United States who will serve as the Accredited Person's contact with FDA;
- 4) Brief description of the applicant, including: type of organization (e.g. not-for-profit institution, commercial business, other type of organization); size of organization (number of employees); number of years in operation; nature of work (e.g. testing or certification laboratory); and information regarding ownership, operation, and control of organization sufficient to assess its degree of independence from device manufacturers and distributors.
- 5) Listing of any national, state, local, or other accreditations; and
- 6) List identifying the devices the applicant seeks to review. Applicants should identify the devices by classification panel or by classification name and citation if seeking to review a subset of eligible devices.

B. Prevention of Conflicts of Interest

You should submit a copy of the written policies and procedures you have established to ensure that the Accredited Person and its employees (including contract employees) involved in the evaluation of 510(k)s are free from conflicts of interest, and to ensure prevention of any individual or organizational conflict of interest or appearance of conflict of interest that might affect the review process.

We will assess these written policies and procedures to ensure that the most common concerns relating to potential conflicts of interest are addressed.

C. Personnel Qualifications

We will consider several factors with respect to personnel qualifications and the preparedness of the applicant to conduct technically competent reviews. You should document these factors in your application and include:

- 1) the written policies and procedures you have established to ensure that 510(k)s are reviewed by qualified personnel;
- 2) the written instructions for the duties and responsibilities of personnel with respect to 510(k) reviews;
- 3) the written personnel qualification standards you have established to ensure that designated personnel are qualified in all of the scientific disciplines addressed by the 510(k)s that you wish to accept for review;
- 4) the documentation (e.g., CVs) to establish that the reviewers of 510(k)s and other involved non-supervisory personnel meet the established criteria for qualified personnel. This includes documentation of education, training, skills, abilities and experience,

- including specialized education and experience needed for the review of class II devices you wish to review;
- 5) the documentation (e.g. CVs) to establish that the supervisor(s) of 510(k) reviewers have sufficient authority and meet the established criteria for qualified supervisory personnel. This includes documentation of education, training, skills, abilities and experience, including any specialized education and experience needed to supervise the review of class II devices you wish to accept for review; and
 - 6) a description of your management structure or, if you use a contractor for 510(k) reviews, the contractor's management structure. The application should describe the position of the individual(s) providing supervision within the management structure and explain how that structure provides for the supervision of the 510(k) reviewers and other personnel involved in the review process.

D. Certification/Agreement Statement

You should provide a commitment, signed by the most responsible individual at the firm, certifying that the Accredited Person, at a minimum, will:

- 1) certify that reported information accurately reflects data reviewed;
- 2) limit work to that for which competence and capacity are available;
- 3) treat information received, records, reports, and recommendations as proprietary information;
- 4) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and
- 5) protect against the use of any officer or employee of the Accredited Person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the Accredited Person, and the officers and employees of the Accredited Person have maintained compliance with requirements relating to financial conflicts of interest.

E. Certification/Training

You should include a statement signed by the most responsible individual at the firm that you will have designated employees attend FDA training for Accredited Persons.

F. Facilities

You should identify the equipment you have available to interface with FDA's electronic data systems (e.g., computer system with a modem, an independent FAX).

IV. What Must an Accredited Person Submit to Review Additional Devices Under the Pilot?

If you are currently accredited under section 523 of the act and wish to expand your accreditation to include review of additional device types included in the pilot described in Section II B, Purpose and Nature of Program, you need only submit:

- 1) information identifying the additional devices you wish to review (e.g., all eligible devices for a specified classification panel or, if seeking to review a subset of eligible devices within a panel, identification of the specific devices by classification name and citation); and
- 2) any modifications to the documents required in Section III C, Personnel Qualifications, that you made to accommodate the review of these additional devices. This may include modified policies and procedures for review of class II devices for which device-specific guidance does not exist.

V. How Can You Obtain Additional Information?

You can obtain additional information on FDAMA through the FDA or CDRH Home Page and/or on 3.5" IBM formatted disks. To request a copy of these documents on disk, FAX a request to the Division of Small Manufacturers Assistance, Attention: Publications, at 301-847-8149.

Also, persons interested in obtaining a copy of the documents may do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information, including text, graphics, and files that may be downloaded to a PC with access to the Web. The FDA Home Page may be accessed at <http://www.fda.gov> and the CDRH Home Page may be accessed at <http://www.fda.gov/cdrh>. Currently available documents for third party programs under FDAMA are listed below:

The following documents are available in the CDRH Home Page:

- 1) FDAMA and related documents
(<http://www.fda.gov/cdrh/modact/modern.html> under "FDAMA" menu item)
- 2) (also available on disk) Premarket Notification 510(k) Regulatory Requirements for Medical Devices (August, 1995)
(<http://www.fda.gov/cdrh/manual/510kp1.html>)
- 3) (also available on disk) In Vitro Diagnostic Products: Guidance for the Preparation of 510(k) Submissions (January, 1997)
(<http://www.fda.gov/cdrh/manual/ivdmanul.html>)
- 4) Third Party Review Instruction Manual (July 1, 1996)
(<http://www.fda.gov/cdrh/dsma/3previewmanual.pdf>)
- 5) Determination of Intended Use for 510(k) Devices - Guidance for Industry and CDRH Staff (January, 1998)
(<http://www.fda.gov/cdrh/modact/k981.html>)

- 6) Guidance on the Recognition and Use of Consensus Standards
(February, 1998) (<http://www.fda.gov/cdrh/modact/k982.html>)
- 7) Guidance on the Use of Standards in Substantial Equivalence
Determinations (March, 2000)
(<http://www.fda.gov/cdrh/ode/guidance/1131.html>)