The areas inspected appear to be in substantial compliance with the applicable requirements of the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or export certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

[The following is an example of a letter intended to be used in situations classified as VAI where an FDA–483 was issued, but all profile classes were found to be acceptable. This type of letter should be issued only when no regulatory action is contemplated, including issuing a warning letter:]

Date:

Name:

Address:

Dear:

The Food and Drug Administration (FDA) conducted an inspection of your firm's (description) facility at (address) on (date). The inspection covered the products described below.

(list of products and their profile classes)

While some adverse practices/conditions were observed during the inspection, they do not appear to warrant consideration of regulatory followup at this time. These problems were reported to you on an FDA–483 (copy enclosed) issued at the conclusion of the inspection. The problems should be corrected and we encourage you to advise us as to your followup actions.

Based on these findings, the agency is prepared to endorse applicable pending premarket (PMA) submissions or Export Certificates for products manufactured at your facility that were specifically inspected. This information is available to Federal agencies when they consider awarding contracts. There may be other products and operations of your firm for which the conclusions from this inspection are not applicable. The agency may separately inspect your firm's facilities to address good manufacturing practices (GMP's) in these areas.

Your firm has an ongoing responsibility to conduct internal self-audits, to ensure you are continuing to maintain conformance with GMP's.

For further information, please contact the following individual at this office:

(name and telephone number)

Sincerely,

Enclosures: FDA–483

Interested persons may, on or before June 3, 1996, submit comments to the Dockets Management Branch (address above). Two copies 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. Received comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96–8185 Filed 3–29–96; 4:05 pm]

**BILLING CODE 4160–01–F**

---

**[Docket No. 96N–0025]**

## Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of the agency's review of premarket notifications for medical devices. To implement the pilot program, FDA is announcing simplified agency procedures and practices to process premarket notifications (510(k)'s) submitted by, and with a review prepared by, third-party review organizations (third parties). In its discretion, FDA will select third parties pursuant to the general statements of policy with respect to competence and freedom from conflicts of interest announced in this document. FDA recognizes that it has long been common practice for some firms to engage third parties to make a preliminary review and assist in the quality control of documents prior to their submission in 510(k)'s. FDA believes a similar third-party effort may be useful to improve the efficiency of the agency's review process. The pilot program will allow FDA to evaluate the feasibility of using the results of a third party's review in lieu of the agency's initial review effort. This action is part of efforts in pursuit of the reinventing Government goals of the National Performance Review.

**DATES:** The pilot program will begin August 1, 1996, and will run for a 2-year period. FDA will apply the pilot program procedures to 510(k)'s received during this period from recognized third parties. FDA is now accepting applications for recognition of prospective third parties and will continue to do so through June 3, 1996. To help prospective third parties prepare these applications, FDA will hold an information session for prospective third parties on April 15, 1996, to review the third-party recognition process and criteria described in this notice, and to answer related questions.

Submit written comments on the pilot program by June 3, 1996.

Submit written comments on the information collection requirements by June 3, 1996. At FDA's request, the Office of Management and Budget (OMB) authorized emergency processing of this information collection. OMB approved the information collection for 90 days, under OMB control no. 0910–0318.

**ADDRESSES:** Prospective third parties should submit an application for recognition, in duplicate, to the Division of Small Manufacturers Assistance (HFZ–220), ATTN: Third-Party Recognition, Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818. 510(k)'s reviewed by third parties should be submitted to the Document Mail Center (HFZ–401), ATTN: Third-Party Review, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

Written comments regarding the pilot program and the information collection requirements may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

Persons interested in attending the information session for prospective third parties should obtain registration information as soon as possible. Copies of a facsimile containing this

information are available from the Center for Devices and Radiological Health's (CDRH's) Facts on Demand system by dialing 1–800–899–0381 or 1–301–827–0111 and requesting document number 258. Internet users can obtain registration information by using the World Wide Web; FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Then select the Topic Index option and then scroll down to the Third Party Review option. Registration information is also available from the electronic docket administered by the Division of Small Manufacturers Assistance and is available to anyone with a video terminal or personal computer with a modem (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 2–Medical Devices Regulations; 8–Third Party Review FR Notice. FDA encourages interested third parties to consider attending this session. FDA will make an initial list of recognized third parties publicly available before commencement of the pilot program, and will update the list as changes occur.

A package of information explaining the Third Party Review Program will be distributed at the information sesssion on April 15, 1996. If you are unable to attend the information session and would like the Third Party Review Program information package, please call 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818 with your name and mailing address, and the package will be mailed after April 15, 1996.

**FOR FURTHER INFORMATION CONTACT:** Eric J. Rechen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

**SUPPLEMENTARY INFORMATION:**

## I. Background

### *A. 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 Federal Food, Drug, and Cosmetic Act (the act), as modified by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. The amendments established in section 513(a) of the act (21 U.S.C. 360c(a)) three device classes and directed FDA to publish regulations classifying each device on the market as of the amendments' enactment. Classification is based on the level of control necessary to provide reasonable assurance of the safety and effectiveness of a device. Class I devices are subject only to general controls, including manufacturer registration, device listing, 510(k), records and reports, and current good manufacturing practice requirements. FDA may, by regulation, exempt a class I device from certain of these requirements, including 510(k) requirements. Class II devices are subject to special controls in addition to general controls, such as promulgation of performance standards, postmarket surveillance, patient registries, and dissemination of guidelines and recommendations. Class III devices are subject to premarket approval and general controls. A preamendments class III device is not required to undergo premarket approval until the effective date of a regulation calling for premarket approval under section 515 of the act (21 U.S.C. 360e).

Section 513(f) of the act contains special classification provisions for postamendments devices. A device introduced on or after the amendments' enactment date (May 28, 1976) is automatically in class III and must receive premarket approval or be reclassified before marketing unless it is *substantially equivalent* to a predicate device (a device marketed before the amendments' enactment, or a device introduced after the amendments' enactment that FDA has reclassified from class III into class I or II).

Section 510(k) of the act provides a means to ensure that manufacturers do not intentionally or unintentionally circumvent the automatic classification provisions of § 513(f). Under § 510(k), a person who intends to begin introduction of a device into commercial distribution is required to report to FDA by submitting a 510(k) at least 90 days in advance. FDA reviews 510(k)'s to determine if a new device is substantially equivalent to a predicate device. For purposes of determining substantial equivalence, a new device may also be compared to a device that FDA has found to be substantially equivalent through the 510(k) process. A device determined by FDA to be substantially equivalent is in the same class and may be introduced to the market subject to the same regulatory controls as the device to which it is substantially equivalent. Before marketing the device, the manufacturer must receive an order, in the form of a letter, by which FDA finds the device to be substantially equivalent. A device determined to be not substantially equivalent is automatically in class III and must receive premarket approval or be reclassified before it is marketed.

The meaning of the term ''substantially equivalent'' is discussed in section 513(i) of the act. Substantial equivalence means, in essence, that a device: (1) Has the same intended use and the same technological characteristics as a predicate 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 legally marketed device and the device does not raise different questions of safety and effectiveness than the predicate device. Substantial equivalence determinations are currently made by scientific review staff within CDRH based primarily upon information provided by a manufacturer's 510(k). FDA has published regulations (part 807 (21 CFR part 807, subpart E)) specifying 510(k) content and procedures. FDA has also developed numerous guidance documents and policy memoranda for the 510(k) program that are available from CDRH's DSMA, as discussed later in this notice.

Since the inception of the 510(k) program in 1976, FDA has received more than 90,000 510(k)'s, approximately 6,000 of which were received in fiscal year (FY) 1995. Approximately 80 percent of 510(k)'s have resulted in substantially equivalent determinations, 2 percent in not substantially equivalent determinations, and the remainder in administrative actions such as withdrawal by the submitter or deletion by FDA due to lack of response by a submitter. During the second half of FY 1995, approximately 20 percent of substantially equivalent determinations were for class I devices, 76 percent were for class II devices, and 4 percent were for class III devices.

### *B. Initial Announcement of the Pilot Program*

On April 6, 1995, FDA announced its intent to conduct a limited pilot program of third-party review of selected 510(k)'s (hereinafter referred to as the April announcement). This initiative is one aspect of FDA's efforts in pursuit of the reinventing Government goals of the National Performance Review. The purpose of the pilot program is to test the feasibility of third-party review of selected 510(k)'s, as an alternative to FDA's primary review.

In the Federal Register of June 1, 1995 (60 FR 28618), FDA published a notice providing an outline of the proposed pilot program (hereinafter referred to as the June 1 notice) and announcing a June 19, 1995, public workshop to

discuss the proposal. The June 1 notice and the April announcement described key elements of the proposed pilot program:

• FDA will designate the types of devices eligible for third-party review. The devices will be in class I or II, involve low- to moderate-risk, and have a clear basis for review. The pilot program will exclude 510(k)'s requiring clinical data for a decision.

• Third parties will be individually accepted by FDA. FDA will outline criteria covering personnel qualifications and controls over potential conflicts of interest.

• Industry participation will be voluntary. A manufacturer that chooses to participate will submit its 510(k) directly to a recognized third party; the third party may assess a fee for its services. Manufacturers that do not wish to participate may continue to submit 510(k)'s to FDA.

• The selected third party will conduct a complete review of the 510(k), document the review, and make a recommendation to FDA. FDA will check the review, make a substantial equivalence decision, and issue a decision letter.

• The pilot program will begin in FY 1996 and will operate for 2 years. FDA will evaluate it during the second year to determine whether it should be continued as is, modified, or terminated.

The June 19 public workshop provided a forum to discuss FDA's proposed approach to implementing third-party review of selected 510(k)'s and a means of obtaining public comments and suggestions that would help FDA refine its plans for the pilot program. Topics discussed at the workshop included: The role of third parties; types of devices eligible for third-party review; safeguards necessary to ensure the quality and integrity of the pilot program; and funding of third-party reviews. More than 200 persons attended the workshop, including representatives of the device industry, potential third parties, consumers, and health professionals. In addition to presentations and comments at the workshop, FDA accepted written comments through July 7, 1995.

In general, these presentations and comments showed broad support for a pilot program. Some industry representatives expressed concern, however, about limitations on the pilot program that may restrict manufacturers' incentive to participate. In particular, they commented that including only low- to moderate-risk devices in the pilot program and limiting third parties' role to making recommendations rather than final decisions might result in marketing clearance decisions that are no faster, and perhaps slower, than those made by FDA alone. In addition, some industry representatives advocated: Standards-based third-party reviews rather than reviews focused on substantial equivalence; increased harmonization with international standards; and reliance on existing accreditation systems and criteria for potential third parties. Only a few manufacturers expressed opposition to the pilot program, arguing that it would divert FDA's resources away from other reviews or result in inconsistent marketing clearance decisions.

Potential third parties expressed strong interest in the pilot program and indicated that they have the capability, independence, and controls to conduct sound and unbiased reviews. Most advocated that FDA rely on existing accreditation systems and criteria for potential third parties, and that the setting of fees should be left to market forces.

Consumer and professional representatives recommended that FDA proceed cautiously with the pilot program. They expressed concern that third-party review could result in some loss of public accountability and that effective controls are needed to ensure technically-competent reviews free of any conflict of interest that could undermine the objectivity of the review process.

In the months following the June 19 workshop, FDA has considered all comments provided at the workshop and in response to the June 1 notice. FDA has attempted to incorporate suggestions to the extent that they are consistent with existing statutory requirements and the pilot program's purpose and timeframe. For example, while FDA continues to believe that the pilot program should be limited to low- to moderate-risk devices, FDA is significantly expanding the number of devices (particularly in vitro diagnostics) eligible for third-party review and is accepting the suggestion that there be a 30-day performance goal for FDA's decisionmaking based on third-party reviews. Given that FDA's cumulative review time is currently averaging approximately 90 days for 510(k) decisions involving class I devices (and is higher for other 510(k) decisions), a 30-day performance goal for FDA decisions under the pilot program in conjunction with a timely third-party review should provide a tangible incentive for manufacturers to participate in the pilot program.

Similarly, while FDA is unaware of any existing accreditation program for potential third parties that is directly suited to 510(k) review—and is therefore unable to incorporate reliance on such an accreditation for purposes of this pilot program—FDA is establishing a streamlined process for third parties to seek participation in the pilot program. This process should not present an undue burden to qualified third parties that are ready to conduct reviews. However, FDA will only recognize third parties that establish stringent criteria regarding potential conflicts of interest. Having third parties who establish such criteria—in conjunction with FDA's oversight of all third-party reviews and potential for more indepth auditing—should ensure the quality and integrity of 510(k) decisions made under the pilot program.

FDA is not adopting the suggestion that it establish a specific performance goal for the timeliness of reviews by third parties. FDA believes such a goal is unnecessary because timeliness of third-party reviews is likely to be a contractual matter between manufacturers and third parties. In addition, market forces will provide an incentive for third parties to perform timely reviews, i.e., timeliness will be an important consideration when a manufacturer decides whether to submit a 510(k) to a particular third party or to FDA.

FDA has received suggestions that third parties be given final decisionmaking authority under the pilot program and that third parties conduct 510(k) reviews that are focused on criteria other than substantial equivalence. FDA is not adopting these suggestions in the pilot program. It is beyond the scope of the pilot program to test an approach that is completely harmonized with other regulatory systems, such as the third-party system of the European Union. The pilot program does contain key elements of the European model, however, and will provide information useful in assessing its potential applicability in this country. FDA remains committed to the goal of global harmonization and will continue to work with its regulatory counterparts toward that end.

FDA welcomes further comments concerning the pilot program. FDA will use comments to make necessary adjustments during implementation of the pilot program and to conduct an evaluation.

## II. Outline of the Third-Party Review Pilot Program

### *A. Purpose*

The overall purpose of the pilot program is to determine whether it is feasible for third parties in the private sector to conduct selected 510(k) reviews that, until now, have been conducted by FDA. This includes determining:

- The willingness of qualified third parties to participate;
- The willingness of manufacturers to submit 510(k)'s to a third party;
- The quality, timeliness, and independence of third-party reviews; and
- Any discernable impacts on FDA resource needs, review times, and decisions, and on the total time needed for manufacturers to obtain 510(k) decisions.

If the pilot approach proves successful, it will: (1) Enable FDA to target its scientific review resources at higher-risk devices while maintaining a high degree of confidence in the review by third parties of low- to moderate-risk devices; and (2) provide manufacturers of eligible devices an alternative review process that can yield more rapid 510(k) decisions. FDA intends the pilot program to test the feasibility of attaining these outcomes.

The pilot program includes safeguards to maintain a high level of quality in the review of 510(k)'s submitted to third parties.

Participation in the pilot is entirely voluntary. Manufacturers may continue to submit 510(k)'s directly to FDA. Manufacturers may also employ the assistance of third parties other than those recognized by FDA, but only 510(k)'s reviewed by recognized third parties will be eligible for the pilot program's simplified processing procedures.

Although the guidance set forth in this notice does not create or confer any rights on any person, and does not operate to bind FDA in any way, it does represent the agency's current thinking on third-party review of 510(k)'s.

### *B. Devices Eligible for Third-Party Review*

During the pilot program, 510(k)'s for the following two categories of devices will be eligible for review by third parties, except when a determination of substantial equivalence necessitates review of clinical data:

- All class I devices that are not exempt from 510(k); and
- Class II devices designated by FDA for inclusion in the pilot program, for which FDA has made device-specific review guidance available.

There are more than 200 types of devices classified by FDA in class I that have not been exempted from 510(k), many of which are in vitro diagnostic devices. FDA is making available a list of these devices (see section III of this document for information on obtaining a copy). FDA currently receives approximately 1,100 510(k)'s per year for these devices.

FDA is also making available a preliminary list of class II devices that it intends to include in the pilot program (see section III of this document for information on obtaining a copy of the list or any associated review guidance). Prior to commencement of the pilot program, and on a quarterly basis during the program's first year, FDA will make review guidance available for a portion of the devices on the list and will update the list to designate those devices as being eligible for third-party review. FDA intends all of the class II devices on the preliminary list to be eligible for third-party review by the end of the first year of the pilot program, but this may be affected by factors such as workload or resource changes in CDRH's Office of Device Evaluation and the extent or nature of public comments received in the development of guidance documents.

Any 510(k) for which clinical data are needed to make a determination of substantial equivalence will continue to be subject to primary review by FDA and will not be processed by FDA under the special procedures for this pilot program. 510(k)'s for the above two categories of devices normally do not contain clinical data and will typically be candidates for inclusion in the pilot program. The need for clinical data is, however, a matter of expert judgment and is often dependent on the nature of any differences (e.g., new indications for use) between the new device and the device to which it is being compared. Manufacturers and third parties 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.

### *C. Recognition of Third Parties*

FDA will recognize those third parties whose reviews of 510(k)'s it will consider during the pilot program. While the number of third parties to be recognized by FDA will necessarily be dependent on the number of qualified applicants and the extent of their review capabilities, FDA believes that participation by 3 to 10 recognized third parties would be sufficient for purposes of the pilot program and would keep the pilot program within manageable limits. When selecting third parties for recognition, FDA will give foremost consideration to those third parties with the most qualified personnel and the most stringent conflict of interest standards that are capable of reviewing a broad range of device types or that are uniquely capable of reviewing specific types of devices. FDA will consider recognition requests from both domestic and foreign third parties.

CDRH will maintain a list of third parties eligible to submit 510(k) reviews to FDA. This list will provide the name, contact person, address, telephone number, and specialty (if any) of organizations that FDA has recognized for participation as third parties in the pilot program.

FDA is announcing that it intends to hold an information session for prospective third parties on April 15, 1996, in Rockville, MD, to review the third-party recognition process and criteria described in this notice, and to answer related questions. FDA encourages interested third parties to consider attending this session before submitting a request for recognition. Persons interested in attending should obtain registration information as soon as possible. Copies of a facsimile containing this information are available from CDRH's Facts on Demand system by dialing 1–800–899–0381 or 1–301–827–0111 and requesting document number 258. Internet users can obtain registration information by using the World Wide Web; FDA's home page address may be accessed at http://www.fda.gov and then select the Medical Devices and Radiological Health option. Then select the Topic Index option and then scroll down to the Third Party Review option. Registration information is also available from the electronic docket administered by the Division of Small Manufacturers Assistance and is available to anyone with a video terminal or personal computer with a modem (1–800–252–1366 or 1–301–594–2741) by making the following menu choices: 2–Medical Device Regulations; 8–Third Party Review FR Notice.

Qualified organizations that wish to become a recognized third party for the pilot program should submit the following materials, in duplicate, no later than June 3, 1996:

1. Information identifying the third party, including its name, contact person, address, telephone number, and fax number. A third party located outside the United States 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 third party's official correspondent with FDA.

2. Identification of the devices the third party seeks to review. If a third party seeks to review only a subset of the devices eligible for third-party review under this pilot program, the devices should be clearly identified, such as by classification panel (i.e., all eligible devices within the panel) or by specific classification name and Code of Federal Regulations citation.

3. Documentation that the third party meets its established criteria, as described in section II.D.1. and II.D.2. of this document, with respect to personnel qualifications and facilities.

4. A copy of the written policies and procedures established by the third party to ensure that it and its employees involved in the third-party review of 510(k)'s are free from conflicts of interest, as outlined in section II.D.3. of this document, and certification that the third party and its employees meet its established criteria.

5. A statement that the third party consents to FDA inspection and copying of all records, correspondence, and other materials relating to any review conducted by the third party under this pilot program, including records on personnel education, training, skills, and experience, all documentation on prevention of conflicts of interest, and the third party's fee schedule and invoices for conducting 510(k) reviews.

6. A statement that the third party will strictly preserve and protect the confidentiality of all information provided by any manufacturer and by FDA.

When these materials are received by DSMA, a date-stamped acknowledgment letter will be faxed to the third party's official correspondent. DSMA will coordinate CDRH's review of these materials and respond to the third party within 30 days of the completion of the time period for submitting such materials with one of the following: A letter of recognition, a denial of recognition, or a request for additional information. CDRH may deny a request for recognition for any reason, including if it determines that the third party's personnel qualifications or criteria for ensuring conflicts of interest are inadequate, or if the third-party's submission does not place it among the most highly qualified candidates. CDRH may deem incomplete and delete a request for recognition if a third party fails to respond to a request for additional information within 10 days. Third parties may make a written request to the Director, Office of Health and Industry Programs, CDRH for reconsideration of a decision to deny or delete a request for recognition.

A list of recognized third parties will be made available to the public through CDRH's Facts-on-Demand facsimile system (1–800–899–0381, document number 967), or the electronic docket (1–800–252–1366) (see section III. of this document for information on obtaining a copy) before commencement of the pilot program. The list will be updated as necessary and will be made available for the duration of the pilot program.

Unless the third party requests that it be removed from FDA's recognition list, or FDA finds for any reason in its sole discretion—including that the third party has not followed recognized rules of ethics or conduct, is not in fact independent, or has knowingly made any material misstatement of fact or circumstances or material misrepresentations of any kind—that the third party is no longer qualified, recognition will continue for the duration of the pilot program. If changes occur that significantly affect any information or certification provided to FDA, it is the responsibility of the third party to provide FDA with updated information and, if necessary, an updated certification, at the earliest possible opportunity.

If FDA has reason to believe that a recognized third party no longer meets the criteria for participation in the pilot program, an opportunity for a meeting with the Director, Office of Health and Industry Programs, CDRH, will be provided prior to any decision concerning removal of the third party from FDA's list of recognized third parties.

Consistent with current practice, FDA will accept 510(k)'s from third parties that have not been recognized, but FDA will give no weight to any review or recommendation provided by the nonrecognized third party and will treat the submission in the same manner as a 510(k) submitted by a consultant.

*D. Criteria for Third Parties*

To be recognized by FDA, a third party should demonstrate that it has the appropriate qualifications and facilities to conduct competent 510(k) reviews, and has instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

1. Personnel Qualifications

FDA expects to recognize third parties that have sufficient personnel, with the necessary education, training, skills, and experience, to evaluate a substantial number of 510(k)'s in those categories of devices it accepts for review. FDA will consider several factors with respect to personnel qualifications when it considers who to recognize as third parties. These include:

(a) Whether the third party 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);

(b) Whether the third party has made available to its personnel clear, written instructions for their duties and responsibilities with respect to 510(k) reviews;

(c) Whether the third party employs personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)'s that the third party accepts for review;

(d) Whether the third party 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

(e) Whether the third party is prepared to conduct technically competent reviews at the time of requesting recognition by FDA.

FDA is making available information on the general education and experience FDA requires of its scientific review personnel (see section III. of this document for information on obtaining a copy). Within CDRH's Office of Device Evaluation, the GS–12 level (as described in the information being made available) is usually considered to be the typical level at which reviewers assume full responsibility for conducting 510(k) reviews. A third party may adopt these criteria as one means of ensuring that its personnel having primary responsibility for review of a 510(k) for a class I device have appropriate education and experience. A third party may develop and apply alternative criteria that result in personnel having education and experience necessary and appropriate to review 510(k)'s for class I devices.

For appropriate review of a particular class II device, FDA will expect specialized education or experience consistent with assuring a technically competent review.

2. Facilities

FDA expects to recognize third parties that have the capability to interface with

FDA electronic data systems. At a minimum, this would include a computer system with a modem and an independent facsimile machine.

3. Prevention of Conflicts of Interest

FDA expects to recognize third parties that will 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 recognize a third party, FDA will consider whether the third party has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest. Although it is not feasible to identify or state categorically or inflexibly all of the criteria for judging that a third party is free of conflicts of interest, the most common conditions that would indicate a potential conflict of interest are:

(a) The third party is owned, operated, or controlled by a device manufacturer or distributor;

(b) The third party or any of its personnel involved in 510(k) reviews has any ownership or other financial interest in any medical device, device manufacturer, or distributor;

(c) The third party or any of its personnel involved in 510(k) reviews participates in the design, manufacture, or distribution of any medical device;

(d) The third party or any of its personnel involved in 510(k) reviews provides consultative services to any device manufacturer or distributor regarding any specific devices;

(e) The third party or any of its personnel involved in 510(k) reviews participates in the preparation of any 510(k); or

(f) The fee charged or accepted by the third party is contingent or based upon the type of recommendation made by the third party.

Nevertheless, a third party may: Assess a fee for its services; conduct other activities, such as objective testing or inspection of devices, if they do not affect the impartiality of 510(k) reviews; and provide information on 510(k) requirements to improve the organization or content of a 510(k) that it is reviewing.

Where a third party uses the services of a contractor for 510(k) reviews, the third party is responsible for the contracted work of its contractor. The third party is to assure that the contractor meets the third party's established criteria for freedom from conflicts of interest.

FDA is making available information on the conflict of interest standards it applies to its own review personnel (see section III. of this document for information on obtaining a copy). A third party may adopt these standards as one means of safeguarding its operations against conflicts of interest.

FDA has considered additional mechanisms to ensure the independence of recognized third parties and to prevent even the appearance of forum shopping by manufacturers. One mechanism considered would be for manufacturers to submit their 510(k)'s first to FDA and then have the agency assign submissions to recognized third parties that are qualified to review them, much like FDA now assigns submissions to internal staff reviewers. Under this mechanism, manufacturers would then negotiate a fee with the third party and pay the fee directly. Although this mechanism would likely be effective in guarding against forum shopping, it has the major disadvantage, for purposes of the pilot program, of necessitating that FDA establish a special processing and assignment system for what could be a relatively large number of 510(k)'s submitted in the short period of the pilot program. It also would restrict manufacturers' ability to negotiate fees, and limit other potentially beneficial competitive influences on the pilot program.

Accordingly, for purposes of this pilot program, manufacturers are to contact recognized third parties directly to request review of their 510(k)'s. FDA may refuse, however, to provide expedited processing of a manufacturer's 510(k)'s and consideration of the accompanying third-party reviews if it appears to FDA, in its sole discretion, that the manufacturer has engaged in forum shopping. Although it is not feasible to identify or state categorically all of the criteria for evaluating whether a manufacturer has forum shopped, three factors that would indicate forum shopping are:

- A manufacturer has obtained reviews of the same 510(k) from more than one third party, or from a third party and directly from FDA;
- A manufacturer has contracted for a substantial number of third-party reviews (ordinarily more than 10 in 1 year) from the same third party when other recognized third parties have the necessary expertise and capacity to perform additional 510(k) reviews; or
- A manufacturer has contracted for reviews from the same third party the sum of fees for which is substantial (ordinarily exceeding $50,000 in 1 year) when other recognized third parties have the necessary expertise and capacity to perform additional 510(k) reviews.

If one (or more) of these factors is present, there will be a presumption of forum shopping and FDA may refuse to provide expedited processing of a manufacturer's 510(k)'s unless the manufacturer can explain why the circumstances do not indicate forum shopping. Manufacturers' avoidance of the last two factors will have the added benefit of enhancing manufacturers' ability to contribute to the evaluation of the pilot program, i.e., manufacturers that contract with more than one third party during the course of the pilot program will have a better basis for assessing how each performs.

*E. Purpose and Nature of a Third-Party Review*

The purpose of a third-party review is to evaluate a manufacturer's 510(k), document the review, and make a recommendation to FDA concerning the substantial equivalence of the device. FDA will provide information on procedures and criteria that it uses for 510(k) reviews in general guidance and in a training program to be made available by FDA before commencement of the pilot program (see section III. of this document for information on obtaining a copy of FDA's general review guidance). Until then, interested persons may consult existing guidance such as HHS Publication FDA 95–4158 ''Premarket Notification 510(k)—Regulatory Requirements for Medical Devices'' (August 1995). This publication provides an overview of device regulations, information on 510(k), FDA requirements concerning 510(k) content and format, a description of the 510(k) review process, copies of particularly important policy memoranda, and additional information useful to manufacturers and third parties. A copy of this publication may be obtained by contacting CDRH's DSMA (see section III. of this document for additional information on obtaining a copy).

FDA encourages third parties to be familiar with the requirements outlined in this publication and in subsequent guidance. The general guidance, as well as any device-specific review guidance made available by FDA, will assist the third party in producing reviews that are acceptable to FDA and that FDA can process in a timely manner.

*F. Training for Recognized Third Parties*

FDA is currently planning to hold one or more training sessions for recognized third parties. (This training is in addition to the prerecognition information session discussed earlier in

this notice.) Recognized third parties are to complete this training before conducting 510(k) reviews under the pilot program. The primary emphasis of this training will be on how to conduct an appropriate review of a 510(k). Depending on demand, one or more sessions may focus on specific types of devices, such as in vitro diagnostic devices. FDA will provide additional information on this training when it sends letters of recognition to third parties participating in the pilot program.

*G. Review Materials to be Submitted to FDA by a Third Party*

Upon completion of its review of a 510(k), a third party should submit the following documentation to FDA, in duplicate:

1. A cover letter signed by the third party's official correspondent clearly identifying: the purpose of the submission; the name and address of the third party; the name and address of the manufacturer; the name of the device (trade name, common or usual name, and FDA classification name); the third party's recommendation with respect to the substantial equivalence of the device; and the date the third party first received the 510(k) from the manufacturer.

2. A letter signed by the manufacturer authorizing the third party to submit the 510(k) to FDA on its behalf and to discuss its contents with FDA.

3. The manufacturer's complete 510(k) conforming to FDA's established requirements relating to content and form of such submissions.

4. A complete review of the 510(k), signed by all personnel who conducted the third-party review and by an individual within the third party responsible for supervising third-party reviews, with a recommendation concerning the substantial equivalence of the device.

5. A certification that the third party continues to meet the personnel qualifications and prevention of conflict of interest criteria reviewed by FDA; that statements made in the third party's review are true and accurate to the best knowledge of the third party; that the third party's review is based on the 510(k) that it is submitting with the review; and that the third party understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

6. Any other information requested in FDA's guidance for third parties.

FDA may not process a 510(k) submitted with a third-party review if this documentation is not included with the submission. Third-party reviews, along with the associated 510(k)'s, should be submitted to CDRH's Document Mail Center (address above). If a part of the material submitted is in a foreign language, it should be accompanied by an English translation verified to be complete and accurate.

*H. Basic Document Processing*

To ensure the integrity of the review process, all third-party review materials and the associated 510(k) are to be submitted directly to FDA by the third party. CDRH's Document Mail Center will receive all submissions, and will then route them to the appropriate review division in CDRH's Office of Device Evaluation. 510(k)'s reviewed and submitted by recognized third parties will bypass the first phases of FDA's normal review process, that is, the acceptance screening and initial scientific review, and will instead be routed directly to the appropriate supervisory official, typically a branch chief. The supervisory official will rely in part on the record of review prepared by the third party and will conduct a brief administrative assessment to determine whether the third party's review is acceptable to FDA. This assessment will apply the same criteria as for 510(k)'s reviewed entirely within FDA. If FDA has questions concerning the submission, the third party will be contacted. The supervisory official will prepare FDA's decision concerning the substantial equivalence of the device. Decision letters and other significant correspondence will be sent to the third party's official correspondent, which will be responsible for communicating with the manufacturer. FDA is establishing a 30-day performance goal for its decisions on 510(k)'s received under the pilot program.

As noted earlier, 510(k)'s submitted by third parties that have not been recognized by the agency will be accepted, but those submissions will not be eligible for processing under the pilot program's simplified procedures. Any such 510(k) will be processed in the same manner as a normal 510(k) submitted by a consultant.

*I. Confidentiality of Information*

A recognized third party is to conscientiously preserve and protect the confidentiality of all information provided to it by a manufacturer or by FDA. Except for authorized FDA employees or as otherwise provided by Federal or State law, no information pertaining to any review, including its existence, is to be made available to any person without the express written permission of the manufacturer employing the third party and written permission by FDA.

The releasability of third-party review information submitted to FDA will be determined by FDA in accordance with the agency's regulations (part 20 (21 CFR part 20) and § 807.95) implementing the Freedom of Information Act and related acts. In general, 510(k) reviews submitted by third parties (just like reviews conducted by FDA staff) will be available for disclosure by FDA after FDA has issued a substantial equivalence decision for a device, unless the information is exempt from public disclosure under part 20. If necessary, a review will be provided to the manufacturer for predisclosure notification pursuant to § 20.61. In addition, information submitted by a third party to obtain FDA's recognition for participation in the pilot program will be available for disclosure by FDA, unless exempt under part 20.

*J. Records*

A recognized third party should maintain complete records of its 510(k) reviews and other information necessary for participation in the pilot program. These records include documentation of the third party's policies and procedures under section II.D. of this document with respect to personnel qualifications and prevention of conflicts of interest; copies of all correspondence and other information to become recognized by FDA; copies of all 510(k) reviews, the associated 510(k)'s, and related correspondence with manufacturers and FDA; information on the identity and qualifications of all personnel who contributed to the technical review of each 510(k); and the third party's fee schedule and invoices for conducting 510(k) reviews. Records should be in English or be accompanied by a complete and accurate English translation. Records should be retained for a reasonable period of time, but no less than 3 years following submission of a review to FDA. All records are subject to FDA inspection and copying.

*K. Fees Assessed by Third Parties*

Recognized third parties may assess a reasonable fee for their services. The fee for a third-party review is a matter to be determined by contract between the third party and the manufacturer, but will be considered by FDA to present a conflict of interest if it is contingent or based upon the type of recommendation made by the third party. As indicated above, the third party's fee schedule and invoices for conducting 510(k) reviews are subject to FDA inspection and copying.

*L. Dates and Duration of the Pilot Program*

The pilot program will begin August 1, 1996, and will run for a 2-year period. FDA will apply the pilot program procedures to 510(k)'s received during this period from recognized third parties. FDA is now accepting applications for recognition of prospective third parties and will continue to do so through June 3, 1996. FDA will closely monitor the operation of the pilot program and may modify its scope or conditions if necessary to protect the public health or to better achieve program objectives. During the second year of the pilot program, FDA will evaluate the pilot program and FDA will then determine whether it should be continued as is, modified, or terminated. FDA intends to complete this evaluation prior to the scheduled ending date for the pilot program.

*M. Safeguards*

The pilot program includes a number of safeguards to maintain a high level of quality in 510(k)'s reviewed by recognized third parties and to minimize risks to the public. Most of these safeguards have been discussed above, and are briefly listed here:

- Limitation of the pilot program to low- to moderate-risk class I or class II devices for which FDA has made review guidance available;
- Exclusion of any 510(k) that requires clinical data for a determination of substantial equivalence;
- FDA assessment and recognition of third parties before their participation in the pilot program;
- Personnel qualifications for third parties equivalent to the level within CDRH's Office of Device Evaluation;
- Criteria to prevent potential conflicts of interest that might affect the review process;
- FDA training for recognized third parties;
- FDA review of third-party reviews/recommendations and FDA's continued responsibility for the issuance of 510(k) decisions;
- Provision for FDA inspection of records, correspondence, and other materials relating to any third-party review;
- FDA monitoring and evaluation of the pilot program; and
- Continued applicability of any other regulatory controls (e.g., medical device reporting of post-marketing adverse events) normally applicable to devices included in the pilot program.

III. Obtaining Additional Information

Additional information on the pilot program can be obtained by contacting CDRH's DSMA at 1–800–638–2041 or 301–443–7491, both at ext. 105, or FAX 301–443–8818. Some information will only be available on the DSMA Facts-on-Demand facsimile system, which is accessed by touch-tone telephone or on the DSMA Electronic Docket, which is accessed via a computer with a modem. Information that DSMA will make available includes:

- This notice;
- Registration information for the information session to be held on April 15, 1996, in Rockville, MD, to review the third-party recognition process and criteria for prospective third parties;
- A checklist for third parties seeking FDA recognition;
- Information on the general education and experience requirements for FDA personnel involved in the technical review of 510(k)'s;
- Information on the conflict of interest standards FDA applies to its employees;
- A list of recognized third parties, updated as necessary (this information will only be available from the DSMA Facts-on-Demand system (1–800–899–0381, document number 967) or Electronic Docket (1–800–252-1366);
- A list of the devices eligible for third-party review, updated at least quarterly;
- Device-specific guidance for class II devices designated as eligible for third-party review;
- General guidance on 510(k) requirements and the content and format of third-party reviews; and
- Any additional information and guidance that FDA finds necessary or appropriate as the pilot program proceeds.

IV. Paperwork Reduction Act of 1995

This voluntary pilot program contains information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). At the agency's request, OMB conducted an emergency review of this information collection, as provided for under 5 CFR 1320.13. OMB approved the information collection within 10 days, as requested by FDA, for the maximum 90 days permitted under 5 CFR 1320.13, under OMB control no. 0910–0318. Persons are not required to respond to a collection of information unless it displays a currently valid OMB control number.

Because the OMB emergency approval of this information collection is valid for only 90 days, FDA is also taking the appropriate steps to obtain a regular approval. Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each collection of information. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c).

To comply with this requirement, FDA is publishing a notice of the information collection. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching data sources, gathering and maintaining the date needed, and completing and reviewing the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title*: Medical Devices; Third-Party Review of Selected Premarket Notifications; Pilot Program

*Description*: This Federal Register notice announces a 2-year, voluntary pilot program to test the feasibility of using third-party reviews to improve the efficiency of FDA's review of premarket notifications under section 510(k) of the act. Participation is entirely voluntary. A third party wishing to participate will submit a request for recognition within 60 days of publication of the Federal Register notice. After reviewing a manufacturer's 510(k), a third party is to forward the 510(k) along with the third party's documented review and recommendation to FDA. Third parties should maintain records of their 510(k) reviews for a reasonable period of time, but no less than 3 years. This information collection will enable FDA to conduct a voluntary pilot program to determine the feasibility of third-party review of 510(k)'s to improve the efficiency of FDA's review of 510(k)'s for low- to moderate-risk devices.

*Description of Respondents*: Businesses or other for-profit, not-for-profit institutions.

Table 1.—Estimated Annual Reporting Burden for Third Parties

| Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours Per Response | Total Hours | Total Capital Costs | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|---|
| II.C.1–5 (Recognition Requests): | | | | | | | |
| First Submission | 15 | 0.5[1] | 7.5 | 24 | 180 | | |
| Additional information | 8 | 0.5[1] | 4.0 | 4 | 16 | | |
| Updates | 10 | 1.0 | 10.0 | 1 | 10 | | |
| 510(k) Reviews | | | | | | | |
| II.G.1–6 | 10 | 50 | 500 | 40 | 20,000 | 57,250 | 28,625 |
| Total | | | | | 20,206 | 57,250 | 28,625 |

[1]These submissions are made in the first year only, the reporting frequency has been averaged over the pilot program's 2-year period to provide an annual frequency.

Table 2.—Estimated Annual Recordkeeping Burden

| Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours Per Recordkeeper | Total Hours | Total Capital Costs | Total Operating & Maintenance Costs |
|---|---|---|---|---|---|---|---|
| II.J. | 10 | 252 | 2,520 | 63 | 630 | | |

Capital costs and operating and maintenance costs are attributable to reporting and are included in the table above.

Organizations and individuals may submit comments regarding this information collection, including suggestions for reducing this burden, by June 3, 1996, and should direct them to the Dockets Management Branch (address above).

Dated: March 25, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96–8149 Filed 4–1–96; 8:45 am]

**BILLING CODE 4160–01–F**

## Investigational New Drugs; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Drug Evaluation and Research (CDER) has placed on certain investigational new drug trials. The committee was established as a 1-year experiment in August 1991. The committee met quarterly through 1992 and currently meets semiannually as a regular program. The committee last met in November 1995. FDA is inviting any interested drug company to use the confidential mechanism to submit to the committee for its review the name and number of any investigational new drug trial placed on clinical hold during the past 12 months that the company wants the committee to review.

**DATES:** The meeting is currently scheduled for June 1996. Drug companies may submit review requests for the June meeting before May 3, 1996.

**ADDRESSES:** Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

**FOR FURTHER INFORMATION CONTACT:** Janet M. Jones, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane (WOC II rm. 6020), Rockville, MD 20857, 301–594–5445.

**SUPPLEMENTARY INFORMATION:** FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational drug. The IND must contain the study protocol, a summary of human and animal experience with the drug, and information about the drug's chemistry and pharmacology. FDA reviews an IND to help ensure the safety and rights of subjects and, in phases 2, 3, and 4 of drug development, to help ensure that the quality of any scientific evaluation of drugs is adequate to permit an evaluation of the drug's efficacy and safety. An investigational new drug for which an IND is in effect is exempt from the premarketing approval requirements that are otherwise applicable and may be shipped lawfully for the purpose of conducting clinical investigations of that drug.

If FDA determines that a proposed or ongoing study may pose significant risks for human subjects or is otherwise seriously deficient, as discussed in the investigational new drug regulations, it may impose a clinical hold on the study. The clinical hold is one of FDA's primary mechanisms for protecting subjects who are involved in investigational new drug trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may