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F

Divider Title: _____

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 part to seek participation in the pilot program. This process should not present an undue burden to qualified third part 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 suggesti 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 sul it 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 foc on criteria other than substantial equivalence. FDA is not adopting t 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 as ing 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 dom ic 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 na 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, 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 part 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 C
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

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P96-7
FOR IMMEDIATE RELEASE
April 3, 1996

Food and Drug Administration
Sharon Snider (301) 443-3285

FDA'S ANNOUNCES REFORMS OF MEDICAL DEVICE PROCEDURES

The Food and Drug Administration today announced initiatives that will streamline, simplify, and reduce the regulatory costs of the medical device industry while maintaining important public health and consumer safety protection.

"Under the leadership of President Clinton, the FDA is adopting a common sense approach to regulating the medical device industry," said Vice President Gore, whose National Performance Review program includes regulatory reform as part of the effort to make the federal government work better and cost less. "The FDA is eliminating unnecessary and burdensome regulations while still maintaining critical public health protection. The result is safe, new medical devices that will be available to the American people in record time."

One initiative, will test whether allowing private organizations to participate in evaluating medical devices will reduce review times and whether strong conflict-of-interest rules can be maintained in such a process.

"This pilot program is another example of FDA's innovative

-More-

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FDA ON THE INTERNET: http://www.fda.gov/

regulatory strategy for the 21st Century," said HHS Secretary Donna E. Shalala. "It explores how the agency can best review relatively low-hazard products while enabling the agency to target its resources where the risks are high."

"The test for any reform is whether it protects the public health," said FDA Commissioner David A. Kessler, M.D. "Our proposal will test whether this speeds up the process and if the integrity of the review can be maintained."

The pilot third party review program will only apply to low and moderate risk devices for which FDA does not require clinical data on safety and effectiveness -- products such as electronic thermometers and surgical gloves. Manufacturers are required to show in premarket notification (510k) applications that products in this category are comparable in safety and effectiveness to a device already legally marketed. FDA receives about 1,500 applications of this type a year.

Participation in the pilot program is voluntary. Firms can opt to have most of the review conducted by a third party, or leave the entire procedure up to FDA.

If an outside review is chosen, the manufacturer selects an FDA-recognized third party and submits to it the marketing application. The organization reviews the product and submits the application, the results of its review, and its recommendation to an FDA supervisor for a final assessment, thereby bypassing the

first phase of FDA's routine review process. An agency decision will be made within 30 days.

FDA will closely monitor the pilot program and make any necessary changes to protect the public health. The program is expected to begin in mid-summer and run for two years. In the near future, FDA will announce the date of an information meeting for prospective third party reviewers to clarify the criteria for their eligibility for participation in the program.

FDA's second initiative is the result of a series of "grass-roots" meetings with medical device manufacturers conducted last year by the agency as part of the National Performance Review. The nation-wide exchanges, which were focused on FDA's inspections for compliance with federal standards, resulted in an initiative jointly developed by FDA and a task force of industry officials. The proposed changes of FDA inspection procedures will apply to firms with a good history of past compliance with FDA requirements.

These changes include:

o advance notification of inspection instead of the routinely conducted unannounced inspections. The prior announcement will enable the firm to prepare for the inspector's visit and be better ready to answer questions;

o an opportunity for firms to note on the official inspection record violative findings that had been immediately corrected. In the past, FDA records listed only the findings, regardless whether or not they had been corrected immediately; and

o a letter from FDA informing firms found in compliance that they had successfully passed the inspection, a recognition that was not accorded in the past.

The program will begin immediately as a pilot project. If successful, it will be expanded to other manufacturers of FDA-regulated products.

The third initiative affecting mainly the food and drug industries, but also applicable to the medical device industry, is a proposal that would streamline and simplify FDA's procedures for complying with the requirements of the National Environmental Policy Act. The proposal, which the agency will soon publish, covers all FDA-regulated product areas and greatly reduces the number of environmental assessments the industries have to prepare for FDA's review.

The agency has found that many of the actions for which it presently requires environmental assessments have no significant effect on the environment, and their elimination will enable FDA to focus greater resources on those areas that present real potential for environmental impact. The agency believes that

these reforms will result in no additional risks to the environment, while saving the industry annually as much as an estimated $15 million, and the agency as much as $1 million.

The announced initiatives are part of a series of over 40 individual reforms that been identified by the FDA and the National Performance Review. The two medical device programs will begin immediately. The proposed elimination of most environmental assessments will be submitted to public comment, with final regulations expected later this year. Meanwhile, some manufacturers are already beginning to submit abbreviated assessments under informal guidance issued by FDA.

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Preliminary List of Class II Devices for Third-Party Review Pilot Program*

(Revised: 29-FEB-96)

Device	Classification Regulation	Division/ Panel	Class/ Tier	Avg. # 510(k)s Per Year	Basis for Third-Party Review (when eligible)
Condom (latex only)	884.5300	DRAERD/OB	II/2	4	- ISO standard; - ASTM standard; - FDA guidance document
Tampons:					
Scented or scented deodorized menstrual tampon	884.5460	DRAERD/OB	II/2	5	- FDA guidance document; - Tampon labeling regs. (21 CFR 801.430)
Unscented menstrual tampon	884.5470	DRAERD/OB	II/1	9	" " "
Diagnostic ultrasound:					
Nonfetal ultrasonic monitor	892.1540	DRAERD/RA	II/2	1	- AIUM/NEMA standards; - FDA guidance document
Ultrasonic pulsed doppler imaging system	892.1550	DRAERD/RA	II/2	10	" " "
Ultrasonic pulsed echo imaging system	892.1560	DRAERD/RA	II/2	20	" " "
Diagnostic ultrasonic transducer	892.1570	DRAERD/RA	II/2	10	
Dental alloys:					
Gold-based alloys and precious metal alloys for clinical use	872.3060	DDIGD/DE	II/2	65	- ANSI/ADA specifications; - FDA guidance document
Base metal alloy	872.3710	DDIGD/DE	II/2	8	" " "

*NOTE: FDA will update this list before commencement of the pilot program (and quarterly thereafter) to begin designating the devices on this list that are eligible for third-party review.

Device	Classification Regulation	Division/ Panel	Class/ Tier	Avg. # 510(k)s Per Year	Basis for Third-Party Review (when eligible)
Clinical electronic thermometer (except tympanic or pacifier thermometers)	880.2910	DDIGD/GH	II/2	15	- ASTM standard; - FDA guidance document
Hypodermic single lumen needle (includes sharps containers other than needle destruction devices; excludes anti-stick and self-destruct needles)	880.5570	DDIGD/GH	II/1	39	- ISO standard; - FDA guidance document
Piston syringe (except anti-stick and self-destruct)	880.5860	DDIGD/GH	II/1	20	- ISO standard; - FDA guidance document
Steam sterilizer (greater than 2 cubic feet)	880.6880	DDIGD/GH	II/2	4	- ANSI/AAMI standard; - FDA guidance document
Intramedullary fixation rod	888.3020	DGRD/OR	II/2	10	- FDA guidance document
External fixators:					
Single/multiple component metallic bone fixation appliances and accessories (except devices with no external components)	888.3030	DGRD/OR	II/2	6	- FDA guidance document
Smooth or threaded metallic bone fixation fastener (except devices with no external components)	888.3040	DGRD/OR	II/2	18	- FDA guidance document

*NOTE: FDA will update this list before commencement of the pilot program (and quarterly thereafter) to begin designating the devices on this list that are eligible for third-party review.

Device	Classification Regulation	Division/ Panel	Class/ Tier	Avg. # 510(k)s Per Year	Basis for Third-Party Review (when eligible)
Human chorionic gonadotropin (HCG) test system intended for the early detection of pregnancy (non-OTC use only)	862.1155(a)	DCLD/CH	II/2	15	- FDA guidance document; - In vitro labeling regs. (21 CFR 809.10)
Hematology quality control mixture	864.8625	DCLD/HE	II/2	8	- FDA guidance document; - In vitro labeling regs. (21 CFR 809.10)
Antimicrobial susceptibility test disc (manual testing only)	866.1620	DCLD/MI	II/2	8	- NCCLS standard; - FDA guidance document; - In vitro labeling regs. (21 CFR 809.10)
C-reactive protein immunological test system	866.5270	DCLD/IM	II/2	3	- FDA guidance document; - In vitro labeling regs. (21 CFR 809.10)
Rheumatoid factor immunological test system	866.5775	DCLD/IM	II/2	3	- FDA guidance document; - In vitro labeling regs. (21 CFR 809.10)
Noninvasive blood pressure measurement devices:					
Blood pressure cuff (manual/non-electronic devices only)	870.1120	DCRND/CV	II/1	7	- FDA guidance document; - ANSI/AAMI standard
Noninvasive blood pressure measurement system (manual/non-electronic devices only)	870.1130	DCRND/CV	II/1	11	" " "

NOTE: FDA will update this list before commencement of the pilot program (and quarterly thereafter) to begin designating the devices on this list that are eligible for third-party review.

Device	Classification Regulation	Division/ Panel	Class/ Tier	Avg. # 510(k)s Per Year	Basis for Third-Party Review (when eligible)
ECG-related devices:					
Electrocardiograph (ECG) lead switching adaptor	870.2350	DCRND/CV	II/1	1	- AAMI standard; - FDA guidance document
Electrocardiograph (ECG) electrode	870.2360	DCRND/CV	II/2	14	- - -
Electrocardiograph (ECG) surface electrode tester	870.2370	DCRND/CV	II/2	0	- - -
Transcutaneous electrical nerve stimulator for pain relief	882.5890	DCRND/NE	II/2	16	- ANSI/AAMI standard; - FDA guidance document
Vitreous aspiration and cutting instrument (includes stand-alone systems and accessories only)	886.4150	DOD/OP	II/2	7	- FDA guidance document
Phacofragmentation system (includes stand-alone systems and accessories only)	886.4670	DOD/OP	II/2	14	- FDA guidance document

NOTE: FDA will update this list before commencement of the pilot program (and quarterly thereafter) to begin designating the devices on this list that are eligible for third-party review.

SECTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
68.1910	ESOPHAGEAL STETHOSCOPE		
	BZW - STETHOSCOPE, ESOPHAGEAL	2	I
68.5620	BREATHING MOUTHPIECE		
	BYP - MOUTHPIECE, BREATHING	1	I
68.5640	MEDICINAL NONVENTILATORY NEBULIZER (ATOMIZER)		
	CCQ - NEBULIZER, MEDICINAL, NON-VENTILATORY (ATOMIZER)	2	I
68.5675	REBREATHING DEVICE		
	BYW - DEVICE, REBREATHING	1	I
68.5700	NONPOWERED OXYGEN TENT		
	FOG - HOOD, OXYGEN, INFANT	1	I
	BYL - TENT, OXYGEN	1	I
68.6810	TRACHEOBRONCHIAL SUCTION CATHETER		
	BSY - CATHETERS, SUCTION, TRACHEOBRONCHIAL	2	I

:ECTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
:62.1030	ALANINE AMINO TRANSFERASE (ALT/SGPT) TEST SYSTEM		
	CJJ - DIAZO, ALT/SGPT	2	I
	CKD - HYDRAZONE COLORIMETRY, ALT/SGPT	2	I
	CKA - NADH OXIDATION/NAD REDUCTION, ALT/SGPT	2	I
	CKC - VANILLIN PYRUVATE, ALT/SGPT	2	I
62.1040	ALDOLASE TEST SYSTEM		
	CJC - FRUCTOSE-1, 6-DIPHOSPHATE AND NADH (U.V.), ALDOLASE	2	I
	CJT - HYDRAZONE COLORIMETRY, ALDOLASE	2	I
:62.1060	DELTA-AMINOLEVULINIC ACID TEST SYSTEM		
	JKL - ACID, DELTA-AMINOLEVULINIC, ION-EXCHANGE COLUMNS WITH COLORIMETRY	2	I
:62.1065	AMMONIA TEST SYSTEM		
	JIG - ELECTRODE, ION-SPECIFIC METHOD, AMMONIA	2	I
	JIF - ENZYMATIC METHOD, AMMONIA	2	I
	JIE - METHOD, ION-EXCHANGE, AMMONIA	2	I
	JID - PHOTOMETRIC METHOD, AMMONIA	2	I
62.1075	ANDROSTENEDIONE TEST SYSTEM		
	CIZ - RADIOIMMUNOASSAY, ANDROSTENEDIONE	2	I
62.1080	ANDROSTERONE TEST SYSTEM		
	CIY - RADIOIMMUNOASSAY, ANDROSTERONE	2	I
.62.1095	ASCORBIC ACID TEST SYSTEM		
	JMA - ACID, ASCORBIC, 2,4-DINITROPHENYLHYDRAZINE (SPECTROPHOTOMETRIC)	2	I
.62.1113	BILIRUBIN (TOTAL AND UNBOUND) IN THE NEONATE TEST SYSTEM		
	MQM - BILIRUBIN (TOTAL AND UNBOUND) IN THE NEONATE TEST SYSTEM	2	I
.62.1115	URINARY BILIRUBIN AND ITS CONJUGATES (NONQUANTITATIVE) TEST SYSTEM		
	JJB - AZO-DYES, COLORIMETRIC, BILIRUBIN & ITS CONJUGATES (URINARY,	2	I
:62.1130	BLOOD VOLUME TEST SYSTEM		
	JKP - CHROMIUM-51, BLOOD VOLUME	2	I
:62.1135	C-PEPTIDES OF PROINSULIN TEST SYSTEM		
	JKD - RADIOIMMUNOASSAY, C-PEPTIDES OF PROINSULIN	2	I
.62.1165	CATECHOLAMINES (TOTAL) TEST SYSTEM		
	CHQ - CHROMATOGRAPHIC/FLUOROMETRIC METHOD, CATECHOLAMINES	2	I
	CHT - ELECTROPHORETIC METHOD, CATECHOLAMINES	2	I
:62.1175	CHOLESTEROL (TOTAL) TEST SYSTEM		
	CHD - ACID, FERRIC ION-SULFURIC, CHOLESTEROL	2	I
	CHH - ENZYMATIC ESTERASE--OXIDASE, CHOLESTEROL	2	I
	CGO - LIEBERMAN-BURCHARD/ABELL-KENDALL, COLORIMETRIC, CHOLESTEROL	2	I
.62.1180	CHYMOTRYPSIN TEST SYSTEM		
	JKW - N-ACETYL-L-TYROSINE ETHYL ESTER (U.V.), CHYMOTRYPSIN	2	I
	JKX - N-BENZOYL-L-TYROSINE ETHYL ESTER (U.V.), CHYMOTRYPSIN	2	I
62.1185	COMPOUND S (11-DEOXYCORTISOL) TEST SYSTEM		
	JKB - RADIOIMMUNOASSAY, COMPOUND S (11-DEOXYCORTISOL)	2	I
.62.1195	CORTICOIDS TEST SYSTEM		
	CHE - RADIOIMMUNOASSAY, CORTICOIDS	2	I
62.1200	CORTICOSTERONE TEST SYSTEM		
	CHA - RADIOIMMUNOASSAY, CORTICOSTERONE	2	I
62.1240	CYSTINE TEST SYSTEM		
	JLD - CHROMATOGRAPHIC, CYSTINE	2	I

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	JLC - NITROPRUSSIDE REACTION (QUALITATIVE, URINE), CYSTINE	2	I
862.1245	DEHYDROEPIANDROSTERONE (FREE AND SULFATE) TEST SYSTEM		
	JKC - RADIOIMMUNOASSAY, DEHYDROEPIANDROSTERONE (FREE AND SULFATE)	2	I
862.1250	DESOXYCORTICOSTERONE TEST SYSTEM		
	JLE - RADIOIMMUNOASSAY, DESOXYCORTICOSTERONE	2	I
862.1260	ESTRADIOL TEST SYSTEM		
	CHP - RADIOIMMUNOASSAY, ESTRADIOL	2	I
862.1265	ESTRIOL TEST SYSTEM		
	CGI - RADIOIMMUNOASSAY, ESTRIOL	2	I
862.1270	ESTROGENS (TOTAL, IN PREGNANCY) TEST SYSTEM		
	CHM - RADIOIMMUNOASSAY, TOTAL ESTROGENS IN PREGNANCY	2	I
862.1275	ESTROGENS (TOTAL, NONPREGNANCY) TEST SYSTEM		
	JHD - RADIOIMMUNOASSAY, TOTAL ESTROGENS, NONPREGNANCY	2	I
862.1280	ESTRONE TEST SYSTEM		
	CGF - RADIOIMMUNOASSAY, ESTRONE	2	I
62.1285	ETIOCHOLANOLONE TEST SYSTEM		
	JLF - RADIOIMMUNOASSAY, ETIOCHOLANOLONE	2	I
862.1300	FOLLICLE-STIMULATING HORMONE TEST SYSTEM		
	CGJ - RADIOIMMUNOASSAY, FOLLICLE-STIMULATING HORMONE	2	I
862.1310	GALACTOSE TEST SYSTEM		
	JIC - COLORIMETRIC METHOD, GALACTOSE	2	I
	JIA - ENZYMATIC METHODS, GALACTOSE	2	I
	JIB - U.V. METHOD, GALACTOSE	2	I
62.1325	GASTRIN TEST SYSTEM		
	CGC - RADIOIMMUNOASSAY, GASTRIN	2	I
62.1330	GLOBULIN TEST SYSTEM		
	CGH - ELECTROPHORETIC, GLOBULIN	2	I
	JGD - NEPHELOMETRIC METHOD, GLOBULIN	2	I
	JGC - TRYPTOPHAN MEASUREMENT (COLORIMETRIC), GLOBULIN	2	I
	JGE - TURBIDIMETRIC METHOD, GLOBULIN	2	I
62.1335	GLUCAGON TEST SYSTEM		
	JME - RADIOIMMUNOASSAY, GLUCAGON	2	I
62.1360	GAMMA-GLUTAMYL TRANSPEPTIDASE AND ISOENZYMES TEST SYSTEM		
	JPZ - COLORIMETRIC METHOD, GAMMA-GLUTAMYL TRANSPEPTIDASE	2	I
	JQA - ELECTROPHORETIC, GAMMA-GLUTAMYL TRANSPEPTIDASE ISOENZYMES	2	I
	JQB - KINETIC METHOD, GAMMA-GLUTAMYL TRANSPEPTIDASE	2	I
62.1370	HUMAN GROWTH HORMONE TEST SYSTEM		
	CFL - RADIOIMMUNOASSAY, HUMAN GROWTH HORMONE	2	I
62.1375	HISTIDINE TEST SYSTEM		
	JMI - CHROMATOGRAPHIC, HISTIDINE	2	I
	JMJ - MICROBIOLOGICAL, HISTIDINE	2	I
62.1385	17-HYDROXYCORTICOSTEROIDS (17-KETOGENIC STEROIDS) TEST SYSTEM		
	CDG - CHROMATOGRAPHY SEPARATION/ZIMMERMAN 17-KETOGENIC STEROIDS	2	I
	JHD - FLUOROMETRIC METHOD, 17-HYDROXYCORTICOSTEROIDS	2	I
	CDB - PORTER SILBER HYDRAZONE, 17-HYDROXYCORTICOSTEROIDS	2	I
	JHE - RADIOASSAY, 17-HYDROXYCORTICOSTEROIDS	2	I
	CCZ - ZIMMERMAN/NORYMBERSKI, 17-KETOGENIC STEROIDS	2	I

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62.1390	5-HYDROXYINDOLE ACETIC ACID/SEROTONIN TEST SYSTEM		
	CDA - ACID, NITROUS AND NITROSONAPHTHOL, 5-HYDROXYINDOLE ACETIC	2	I
62.1395	17-HYDROXYPROGESTERONE TEST SYSTEM		
	JLX - RADIOIMMUNOASSAY, 17-HYDROXYPROGESTERONE	2	I
62.1400	HYDROXYPROLINE TEST SYSTEM		
	JMM - COLUMN CHROMATOGRAPHY & COLOR DEVELOPMENT, HYDROXYPROLINE	2	I
	JMN - EXTRACTION PLUS CHROMATOGRAPHY WITH COLOR BY NINHYDRIN, HYDROXYPROLINE	2	I
62.1405	IMMUNOREACTIVE INSULIN TEST SYSTEM		
	CFP - RADIOIMMUNOASSAY, IMMUNOREACTIVE INSULIN	2	I
62.1410	IRON (NON-HEME) TEST SYSTEM		
	JIZ - ATOMIC ABSORPTION, IRON (NON-HEME)	2	I
	CFM - BATHOPHENANTHROLINE, COLORIMETRY, IRON (NON-HEME)	2	I
	JIY - PHOTOMETRIC METHOD, IRON (NON-HEME)	2	I
	JJA - RADIO-LABELED IRON METHOD, IRON (NON-HEME)	2	I
62.1415	IRON-BINDING CAPACITY TEST BINDING		
	JQF - BATHOPHENANTHROLINE, IRON BINDING CAPACITY	2	I
	JMO - FERROZINE (COLORIMETRIC) IRON BINDING CAPACITY	2	I
	JQG - RADIOMETRIC, FE59, IRON BINDING CAPACITY	2	I
	JQE - RESIN, ION-EXCHANGE, ASCORBIC ACID, COLORIMETRY, IRON BINDING CAPACITY	2	I
	JQD - RESIN, ION-EXCHANGE, THIOGLYCOLIC ACID, COLORIMETRY, IRON BINDING	2	I
62.1430	17-KETOSTEROIDS TEST SYSTEM		
	CDE - CHROMATOGRAPHIC SEPARATION/ZIMMERMAN, 17-KETOSTEROIDS	2	I
	CCY - ZIMMERMAN (SPECTROPHOTOMETRIC), 17-KETOSTEROIDS	2	I
62.1435	URINARY KETONES (NONQUANTITATIVE) TEST SYSTEM		
	JIN - NITROPRUSSIDE, KETONES (URINARY, NON-QUANT.)	2	I
62.1450	LACTIC ACID TEST SYSTEM		
	KHP - ACID, LACTIC, ENZYMATIC METHOD	2	I
62.1460	LEUCINE AMINOPEPTIDASE TEST SYSTEM		
	JGG - L-LEUCINE-4-NITROANILIDE (COLORIMETRIC), LEUCINE ARYLAMIDASE	2	I
	CDC - L-LEUCYL B-NAPHTHYLAMIDE, LEUCINE AMINOPEPTIDASE	2	I
62.1465	LIPASE TEST SYSTEM		
	CHI - LIPASE-ESTERASE, ENZYMATIC, PHOTOMETRIC, LIPASE	2	I
	CFG - OIL EMULSION/THYMOLPHTHALEIN (TITRIMETRIC), LIPASE	2	I
	CET - OLIVE OIL EMULSION (TURBIDIMETRIC), LIPASE	2	I
62.1475	LIPOPROTEIN TEST SYSTEM		
	JHM - COLORIMETRIC METHOD, LIPOPROTEINS	2	I
	JHO - ELECTROPHORETIC SEPARATION, LIPOPROTEINS	2	I
	JHL - MICRODENSITOMETRY METHOD, LIPOPROTEINS	2	I
	JHQ - NEPHELOMETRIC METHOD, LIPOPROTEINS	2	I
	JHP - RADIAL IMMUNODIFFUSION, LIPOPROTEINS	2	I
	JHN - TURBIDIMETRIC METHOD, LIPOPROTEINS	2	I
862.1485	LUTEINIZING HORMONE TEST SYSTEM		
	CEP - RADIOIMMUNOASSAY, LUTEINIZING HORMONE	2	I
862.1495	MAGNESIUM TEST SYSTEM		
	JGI - ATOMIC ABSORPTION, MAGNESIUM	2	I
	CFA - ELECTRODE, ION SPECIFIC, MAGNESIUM	2	I
	JGJ - PHOTOMETRIC METHOD, MAGNESIUM	2	I

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	CFO - TITRIMETRIC, MAGNESIUM	2	I
862.1500	MALIC DEHYDROGENASE TEST SYSTEM		
	JMS - ACID, OXALACETIC AND NADH OXIDATION (U.V.), MALIC DEHYDROGENASE	2	I
862.1505	MUCOPOLYSACCHARIDES TEST SYSTEM		
	JQN - COLORIMETRIC, MUCOPOLYSACCHARIDES	2	I
862.1510	URINARY NITRITE (NONQUANTITATIVE) TEST SYSTEM		
	JMT - DIAZO (COLORIMETRIC), NITRITE (URINARY, NON-QUANT)	2	I
862.1520	5'-NUCLEOTIDASE TEST SYSTEM		
	CED - 5-AMP-PHOSPHATE RELEASE (COLORIMETRIC TEST), 5'-NUCLEOTIDASE	2	I
862.1530	PLASMA ONCOMETRY TEST SYSTEM		
	JNX - MEMBRANE OSMOMETRY, PLASMA ONCOMETRY	2	I
862.1535	ORNITHINE CARBAMYL TRANSFERASE TEST SYSTEM		
	JMY - CITRULLINE, ARSENATE, NESSLER (COLORIMETRY), ORNITHINE CARBAMYL	2	I
862.1540	OSMOLALITY TEST SYSTEM		
	JMZ - COMPARISON OF FREEZING POINTS & STDS. OF KNOWN OSMOTIC PRESSURE,	2	I
	JNA - VAPOR PRESSURE, OSMOLALITY OF SERUM & URINE	2	I
862.1542	OXALATE TEST SYSTEM		
	LPW - SYSTEM, TEST, OXALATE	2	I
862.1550	URINARY PH (NONQUANTITATIVE) TEST SYSTEM		
	CEN - DYE-INDICATOR, PH (URINARY, NON-QUANT.)	2	I
862.1560	URINARY PHENYLKETONES (NONQUANTITATIVE) TEST SYSTEM		
	CES - CHROMOGENESIS, PHENYLKETONES (URINARY, NON-QUANT.)	2	I
	JGK - FERRIC CHLORIDE, PHENYLKETONES (URINARY, NON-QUANT.)	2	I
862.1570	PHOSPHOHEXOSE ISOMERASE TEST SYSTEM		
	JNE - GLUCOSE-6-PHOSPHATE (COLORIMETRIC), PHOSPHOHEXOSE ISOMERASE	2	I
	KLJ - NAD REDUCTION (U.V.), PHOSPHOHEXOSE ISOMERASE	2	I
862.1580	PHOSPHORUS (INORGANIC) TEST SYSTEM		
	CEO - PHOSPHOMOLYBDATE (COLORIMETRIC), INORGANIC PHOSPHORUS	2	I
862.1590	PORPHOBILINOGEN TEST SYSTEM		
	JNF - ION-EXCHANGE RESIN, EHRLICH'S REAGENT, PORPHOBILINOGEN	2	I
862.1595	PORPHYRINS TEST SYSTEM		
	JKJ - FLUOROMETRIC MEASUREMENT, PORPHYRINS	2	I
862.1605	PREGNANEDIOL TEST SYSTEM		
	JLP - SPECTROPHOTOMETRIC METHOD, PREGNANEDIOL	2	I
862.1610	PREGNANETRIOL TEST SYSTEM		
	JLR - GAS CHROMATOGRAPHY, PREGNANETRIOL	2	I
	JLQ - SPECTROPHOTOMETRIC METHOD, PREGNANETRIOL	2	I
862.1615	PREGNENOLONE TEST SYSTEM		
	JNG - RADIOIMMUNOASSAY, PREGNENOLONE	2	I
862.1620	PROGESTERONE TEST SYSTEM		
	JLS - RADIOIMMUNOASSAY, PROGESTERONE	2	I
862.1625	PROLACTIN (LACTOGEN) TEST SYSTEM		
	CFT - RADIOIMMUNOASSAY, PROLACTIN (LACTOGEN)	2	I
862.1630	PROTEIN (FRACTIONATION) TEST SYSTEM		
	JQJ - DENSITOMETERIC, PROTEIN FRACTIONATION	2	I
	CEF - ELECTROPHORETIC, PROTEIN FRACTIONATION	2	I
	JQK - IMMUNODIFFUSION, PROTEIN FRACTIONATION	2	I

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862.1645	URINARY PROTEIN OR ALBUMIN (NONQUANTITATIVE) TEST SYSTEM		
	JIR - INDICATOR METHOD, PROTEIN OR ALBUMIN (URINARY, NON-QUANT.)	2	I
	JIQ - TURBIDIMETRIC METHOD, PROTEIN OR ALBUMIN (URINARY, NON-QUANT.)	2	I
862.1650	PYRUVATE KINASE TEST SYSTEM		
	JNJ - PHOSPHOENOL PYRUVATE, ADP, NADH, PYRUVATE KINASE	2	I
862.1655	PYRUVIC ACID TEST SYSTEM		
	JLT - ACID, PYRUVIC, ENZYMATIC (U.V.)	2	I
862.1660	QUALITY CONTROL MATERIAL (ASSAYED AND UNASSAYED)		
	JJS - CONTROLS FOR BLOOD-GASES, (ASSAYED AND UNASSAYED)	2	I
	JJR - ELECTROLYTE CONTROLS (ASSAYED AND UNASSAYED)	2	I
	JJT - ENZYME CONTROLS (ASSAYED AND UNASSAYED)	2	I
	JJY - MULTI-ANALYTE CONTROLS, ALL KINDS (ASSAYED AND UNASSAYED)	2	I
	JJX - SINGLE (SPECIFIED) ANALYTE CONTROLS (ASSAYED AND UNASSAYED)	2	I
	JJW - URINALYSIS CONTROLS (ASSAYED AND UNASSAYED)	2	I
862.1680	TESTOSTERONE TEST SYSTEM		
	CDZ - RADIOIMMUNOASSAY, TESTOSTERONES AND DIHYDROTESTOSTERONE	2	I
862.1705	TRIGLYCERIDES TEST SYSTEM		
	JGY - COLORIMETRIC METHOD, TRIGLYCERIDES	2	I
	JGW - FLUOROMETRIC METHOD, TRIGLYCERIDES	2	I
	CDT - LIPASE HYDROLYSIS/GLYCEROL KINASE ENZYME, TRIGLYCERIDES	2	I
	CEA - TLC CHROMATOGRAPHIC SEPARATION TRIGLYCERIDES	2	I
	JGX - TURBIDIMETRIC METHOD, TRIGLYCERIDES	2	I
862.1725	TRYPSIN TEST SYSTEM		
	JNO - N-BENZOYL-L-ARGININE ETHYL ESTER (U.V.), TRYPSIN	2	I
	JNN - P-TOLUENESULPHONYL-L-ARGININE METHYL ESTER (U.V.), TRYPSIN	2	I
862.1730	FREE TYROSINE TEST SYSTEM		
	CDR - 1-NITROSO-2-NAPHTHOL (FLUOROMETRIC), FREE TYROSINE	2	I
862.1775	URIC ACID TEST SYSTEM		
	LFQ - ACID, URIC, ACID REDUCTION OF FERRIC ION	2	I
	CDH - ACID, URIC, PHOSPHOTUNGSTATE REDUCTION	2	I
	KNK - ACID, URIC, URICASE (COLORIMETRIC)	2	I
	JHB - ACID, URIC, URICASE (COLORIMETRIC)	2	I
	JHA - ACID, URIC, URICASE (GASOMETRIC)	2	I
	JHC - ACID, URIC, URICASE (OXYGEN RATE)	2	I
	CDO - ACID, URIC, URICASE (U.V.)	2	I
862.1780	URINARY CALCULI (STONES) TEST SYSTEM		
	JNP - INFRARED SPECTROSCOPY MEASUREMENT, URINARY CALCULI (STONE)	2	I
	JNQ - QUALITATIVE CHEMICAL REACTIONS, URINARY CALCULI (STONE)	2	I
862.1785	URINARY UROBILINOGEN (NONQUANTITATIVE) TEST SYSTEM		
	CDM - DIAZONIUM COLORIMETRY, UROBILINOGEN (URINARY, NON-QUANT.)	2	I
862.1790	UROPORPHYRIN TEST SYSTEM		
	JNZ - FLUOROMETRIC, UROPORPHYRIN	2	I
	JQL - SPECTROPHOTOMETRIC, UROPORPHYRIN	2	I
862.1795	VANILMANDELIC ACID TEST SYSTEM		
	CDF - ACID, VANILMANDELIC, DIAZO, P-NITROANILINE/VANILLIN	2	I
	CDK - ACID, VANILMANDELIC, ELECTROPHORETIC SEPARATION	2	I
862.1805	VITAMIN A TEST SYSTEM		

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	JOA - ACID, TRIFLUOROACETIC, VITAMIN A, HEXANE EXTRACTION	2	I
62.1820	XYLOSE TEST SYSTEM		
	JOC - COLORIMETRIC, XYLOSE	2	I
	JQM - P-BROMOANILINE, XYLOSE	2	I
62.2140	CENTRIFUGAL CHEMISTRY ANALYZER FOR CLINICAL USE		
	JJG - ANALYZER, CHEMISTRY, CENTRIFUGAL, FOR CLINICAL USE	2	I
62.2150	CONTINUOUS FLOW SEQUENTIAL MULTIPLE CHEMISTRY ANALYZER FOR CLINICAL USE		
	JJC - ANALYZER, CHEMISTRY (SEQUENTIAL MULTIPLE, CONTINUOUS FLOW) CLINICAL	2	I
62.2160	DISCRETE PHOTOMETRIC CHEMISTRY ANALYZER FOR CLINICAL USE		
	JJE - ANALYZER, CHEMISTRY (PHOTOMETRIC, DISCRETE), FOR CLINICAL USE	2	I
62.2170	MICRO CHEMISTRY ANALYZER FOR CLINICAL USE		
	JJF - ANALYZER, CHEMISTRY, MICRO, FOR CLINICAL USE	2	I
62.2300	COLORIMETER, PHOTOMETER, OR SPECTROPHOTOMETER FOR CLINICAL USE		
	JJQ - COLORIMETER, PHOTOMETER, SPECTROPHOTOMETER FOR CLINICAL USE	2	I
62.2400	DENSITOMETER/SCANNER (INTEGRATING, REFLECTANCE, TLC, RADIOCHROMATOGRAM FOR.) CLI		
	JQT - DENSITOMETER/SCANNER (INTEGRATING, REFLECTANCE, TLC, RADIOCHROMAT.)	2	I
62.2500	ENZYME ANALYZER FOR CLINICAL USE		
	JJI - ANALYZER, ENZYME, FOR CLINICAL USE	2	I
62.2540	FLAME EMISSION PHOTOMETER FOR CLINICAL USE		
	JJO - FLAME EMISSION PHOTOMETER FOR CLINICAL USE	2	I
62.2560	FLUOROMETER FOR CLINICAL USE		
	KHO - FLUOROMETER, FOR CLINICAL USE	2	I
62.2680	MICROTITRATOR FOR CLINICAL USE		
	JRA - MICROTITRATOR, FOR CLINICAL USE	2	I
62.2700	NEPHELOMETER FOR CLINICAL USE		
	JQX - NEPHELOMETER, FOR CLINICAL USE	2	I
62.2730	OSMOMETER FOR CLINICAL USE		
	JJM - OSMOMETER FOR CLINICAL USE	2	I
62.2750	PIPETTING AND DILUTING SYSTEM FOR CLINICAL USE		
	JQW - STATION, PIPETTING AND DILUTING, FOR CLINICAL USE	2	I
62.2900	AUTOMATED URINALYSIS SYSTEM		
	KQO - AUTOMATED URINALYSIS SYSTEM	2	I

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(none)

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72.3400	KARAYA AND SODIUM BORATE WITH OR WITHOUT ACACIA DENTURE ADHESIVE		
	KOM - ADHESIVE, DENTURE, ACACIA AND KARAYA WITH SODIUM BORATE	1	I
72.3700	DENTAL MERCURY (U.S.P)		
	ELY - MERCURY	2	I
72.4200	DENTAL HANDPIECES AND ACCESSORIES		
	EBW - CONTROLLER, FOOT, HANDPIECE AND CORD	2	I
	EFB - HANDPIECE, AIR-POWERED, DENTAL	2	I
	EFA - HANDPIECE, BELT AND/OR GEAR DRIVEN, DENTAL	2	I
	EGS - HANDPIECE, CONTRA- AND RIGHT-ANGLE ATTACHMENT, DENTAL	2	I
	EKX - HANDPIECE, DIRECT DRIVE, AC-POWERED	2	I
	EKY - HANDPIECE, WATER-POWERED	2	I

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74.1070	SHORT INCREMENT SENSITIVITY INDEX (SISI) ADAPTER		
	ETR - ADAPTOR, SHORT INCREMENT SENSITIVITY INDEX (SISI)	2	I
74.1500	GUSTOMETER		
	ETM - GUSTOMETER	2	I
74.1800	AIR OR WATER CALORIC STIMULATOR		
	KHH - STIMULATOR, CALORIC-AIR	2	I
	ETP - STIMULATOR, CALORIC-WATER	2	I
74.1925	TOYNBEE DIAGNOSTIC TUBE		
	ETK - TUBE, TOYNBEE DIAGNOSTIC	2	I
74.3300	HEARING AID		
	ESD - HEARING-AID, AIR-CONDUCTION	2	I
74.4100	EPISTAXIS BALLOON		
	EMX - BALLOON, EPISTAXIS	2	I
74.5300	ENT EXAMINATION AND TREATMENT UNIT		
	ETF - UNIT, EXAMINING/TREATMENT, ENT	2	I
74.5550	POWERED NASAL IRRIGATOR		
	KMA - IRRIGATOR, POWERED NASAL	2	I
74.5840	ANTISTAMMERING DEVICE		
	KTH - DEVICE, ANTI-STAMMERING	2	I

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6.5160	UROLOGICAL CLAMPS FOR MALES		
	FHA - CLAMP, PENILE	1	I
6.5210	ENEMA KIT		
	FCE - KIT, ENEMA, (FOR CLEANING PURPOSE)	2	I
6.5250	URINE COLLECTOR AND ACCESSORIES		
	FAQ - BAG, URINE COLLECTION, LEG, FOR EXTERNAL USE	1	I

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64.5240	AUTOMATED BLOOD CELL DILUTING APPARATUS		
	GKH - APPARATUS, AUTOMATED BLOOD CELL DILUTING	2	I
64.7040	ADENOSINE TRIPHOSPHATE RELEASE ASSAY		
	KHF - ADENINE NUCLEOTIDE QUANTITATION	2	I
	JWR - ATP RELEASE (LUMINESCENCE)	2	I
64.8950	RUSSEL VIPER VENOM REAGENT		
	GIR - REAGENT, RUSSEL VIPER VENOM	2	I

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0.5270	NEONATAL EYE PAD		
	FOK - PAD, NEONATAL EYE	2	I
0.5420	PRESSURE INFUSOR FOR I.V. BAG		
	KZD - INFUSOR, PRESSUE, FOR I.V. BAGS	2	I
0.5680	PEDIATRIC POSITION HOLDER		
	FRP - HOLDER, INFANT POSITION	2	I
0.6250	PATIENT EXAMINATION GLOVE		
	LZB - FINGER COT	1	I
	FMC - GLOVE, PATIENT EXAMINATION	1	I
	LYY - GLOVE, PATIENT EXAMINATION, LATEX	1	I
	LZA - GLOVE, PATIENT EXAMINATION, POLY	1	I
	LZC - GLOVE, PATIENT EXAMINATION, SPECIALTY	1	I
	LYZ - GLOVE, PATIENT EXAMINATION, VINYL	1	I
80.6375	PATIENT LUBRICANT		
	KMJ - LUBRICANT, PATIENT	2	I
80.6760	PROTECTIVE RESTRAINT		
	BRT - RESTRAINT, PATIENT, CONDUCTIVE	3	I
	FMQ - RESTRAINT, PROTECTIVE	3	I

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5.5060	PREALBUMIN INNUMOLOGICAL TEST SYSTEM		
	JZJ - PREALBUMIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DDS - PREALBUMIN, FITC, ANTIGEN, ANTISERUM, CONTROL	2	I
6.5065	HUMAN ALLOTYPIC MARKER IMMUNOLOGICAL TEST SYSTEM		
	DHF - D/KM-1, ANTIGEN, ANTISERUM, CONTROL	2	I
	OGX - NG1M(A), ANTIGEN, ANTISERUM, CONTROL	2	I
	DHI - NG3M(BO), ANTIGEN, ANTISERUM, CONTROL	2	I
	DHQ - NG3M(G), ANTIGEN, ANTISERUM, CONTROL	2	I
	DHY - NG4M(A), ANTIGEN, ANTISERUM, CONTROL	2	I
6.5160	BETA-GLOBULIN IMMUNOLOGICAL TEST SYSTEM		
	DCJ - BETA-GLOBULIN, ANTIGEN, ANTISERUM, CONTROL	2	I
6.5200	CARBONIC ANHYDRASE B AND C IMMUNOLOGICAL TEST SYSTEM		
	ODH - CARBONIC ANHYDRASE B, ANTIGEN, ANTISERUM, CONTROL	2	I
	ODE - CARBONIC ANHYDRASE C, ANTIGEN, ANTISERUM, CONTROL	2	I
	KTK - REAGENT, IMMUNOASSAY, CARBONIC ANHYDRASE B AND C	2	I
6.5330	FACTOR XIII A, S IMMUNOLOGICAL TEST SYSTEM		
	DBT - FACTOR XIII A, S, ANTIGEN, ANTISERUM, CONTROL	2	I
6.5400	ALPHA-GLOBULIN IMMUNOLOGICAL TEST SYSTEM		
	MGA - ALPHA-1 MICROGLOBULIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DCO - ALPHA-GLOBULIN, ANTIGEN, ANTISERUM, CONTROL	2	I
6.5420	ALPHA-1-GLYCOPROTEINS IMMUNOLOGICAL TEST SYSTEM		
	LKL - ALPHA-1-ACID-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DEX - ALPHA-1-B-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DEN - ALPHA-1-T-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
6.5425	ALPHA-2-GLYCOPROTEINS IMMUNOLOGICAL TEST SYSTEM		
	DBC - ALPHA 2, 2N-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DAW - ALPHA-2-AP-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
	DEJ - ALPHA-2-GLYCOPROTEINS, ANTIGEN, ANTISERUM, CONTROL	2	I
	DEF - ALPHA-2-HS-GLYCOPROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
66.5430	BETA-2-GLYCOPROTEIN I IMMUNOLOGICAL TEST SYSTEM		
	DDN - BETA-2-GLYCOPROTEIN I, ANTIGEN, ANTISERUM, CONTROL	2	I
66.5440	BETA-2-GLYCOPROTEIN III IMMUNOLOGICAL TEST SYSTEM		
	DDK - BETA-2-GLYCOPROTEIN III, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5560	LACTIC DEHYDROGENASE IMMUNOLOGICAL TEST SYSTEM		
	DET - LACTIC DEHYDROGENASE, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5570	LACTOFERRIN IMMUNOLOGICAL TEST SYSTEM		
	DEG - LACTOFERRIN, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5590	LIPOPROTEIN X IMMUNOLOGICAL TEST SYSTEM		
	DEL - LIPOPROTEIN X, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5715	PLASMINOGEN IMMUNOLOGICAL TEST SYSTEM		
	DDX - PLASMINOGEN, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5735	PROTHROMBIN IMMUNOLOGICAL TEST SYSTEM		
	DDF - PROTHROMBIN, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5765	RETINOL-BINDING PROTEIN IMMUNOLOGICAL TEST SYSTEM		
	CZS - RETINOL-BINDING PROTEIN, ANTIGEN, ANTISERUM, CONTROL	2	I
366.5890	INTER-ALPHA TRYPSIN INHIBITOR IMMUNOLOGICAL TEST SYSTEM		
	CZO - INTER-ALPHA TRYPSIN INHIBITOR, ANTIGEN, ANTISERUM, CONTROL	2	I

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	DEC - INTER-ALPHA TRYPSIN INHIBITOR, FITC, ANTIGEN, ANTISERUM, CONTROL	2	I

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52.1660	QUALITY CONTROL MATERIAL (ASSAYED AND UNASSAYED)		
	MKA - KIT, DIRECT ANTIGEN, NEGATIVE CONTROL	2	I
	MJZ - KIT, DIRECT ANTIGEN, POSITIVE CONTROL	2	I
	MJY - KIT, SEROLOGICAL, NEGATIVE CONTROL	2	I
	MJX - KIT, SEROLOGICAL, POSITIVE CONTROL	2	I
56.2390	TRANSPORT CULTURE MEDIUM		
	JSL - CULTURE MEDIA, ANAEROBIC TRANSPORT	2	I
	JSM - CULTURE MEDIA, NON-PROPAGATING TRANSPORT	2	I
	JSN - CULTURE MEDIA, PROPAGATING TRANSPORT	2	I
56.2660	MICROORGANISM DIFFERENTIATION AND IDENTIFICATION DEVICE		
	MCB - ANTIGEN, C. DIFFICILE	2	I
	LIB - DEVICE, GENERAL PURPOSE, MICROBIOLOGY, DIAGNOSTIC	2	I
	JTO - DISCS, STRIPS AND REAGENTS, MICROORGANISM DIFFERENTIATION	2	I
	MJM - DNA PROBE, GARDNERELLA VAGINALIS	2	I
	MJK - DNA PROBE, TRICHOMONAS VAGINALIS	2	I
	MLA - DNA PROBE, YEAST	2	I
	LQM - GRAM NEGATIVE IDENTIFICATION PANEL	2	I
	LQL - GRAM POSITIVE IDENTIFICATION PANEL	2	I
	LRH - INSTRUMENT FOR AUTO READER OF OVERNIGHT MICROORGANISM IDENTIFICATION	2	I
	JSP - KIT, ANAEROBIC IDENTIFICATION	2	I
	JST - KIT, FASTIDIOUS ORGANISMS	2	I
	JSR - KIT, IDENTIFICATION, DERMATOPHYTE	2	I
	JSS - KIT, IDENTIFICATION, ENTEROBACTERIACEAE	2	I
	JSW - KIT, IDENTIFICATION, GLUCOSE NONFERMENTER	2	I
	JSY - KIT, IDENTIFICATION, MYCOBACTERIA	2	I
	JSZ - KIT, IDENTIFICATION, PSEUDOMONAS	2	I
	JXB - KIT, IDENTIFICATION, YEAST	2	I
	JWX - KIT, SCREENING, STAPHYLOCOCCUS AUREUS	2	I
	JWZ - KIT, SCREENING, TRICHOMONAS	2	I
	JXA - KIT, SCREENING, URINE	2	I
	JXC - KIT, SCREENING, YEAST	2	I
	LJG - QUALITY CONTROL SLIDES	2	I
	LLH - REAGENTS, CLOSTRIDIUM DIFFICILE TOXIN	2	I
66.2850	AUTOMATED ZONE READER		
	KZK - READER, ZONE, AUTOMATED	2	I
66.2900	MICROBIOLOGICAL SPECIMEN COLLECTION AND TRANSPORT DEVICE		
	LKS - DEVICE, PARASITE CONCENTRATION	2	I
	LIO - DEVICE, SPECIMEN COLLECTION	2	I
	JTW - SYSTEM, TRANSPORT, AEROBIC	2	I
	JTX - TRANSPORT SYSTEMS, ANAEROBIC	2	I
366.3040	ASPERGILLUS SPP. SEROLOGICAL REAGENTS		
	JWT - ANTIGEN, CF, ASPERGILLUS SPP.	2	I
	KFG - ANTISERUM, POSITIVE CONTROL, ASPERGILLUS SPP.	2	I
366.3110	CAMPYLOBACTER FETUS SEROLOGICAL REAGENTS		
	GSP - ANTISERUM, FLUORESCENT, CAMPYLOBACTER FETUS	2	I
	LYR - CAMPYLOBACTER PYLORI	2	I
	LQP - CAMPYLOBACTER SPP.	2	I

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	LQO - DNA-REAGENTS, CAMPYLOBACTER SPP.	2	I
6.3120	CHLAMYDIA SEROLOGICAL REAGENTS		
	GPW - ANTIGEN, CF, PSITTACOSIS (CHLAMYDIA GROUP)	2	I
	LKI - ANTISERA, FLUORESCENT, CHLAMYDIA SPP.	2	I
	LKH - ANTISERA, IMMUNOPEROXIDASE, CHLAMYDIA SPP.	2	I
	GPT - ANTISERUM, CF, PSITTACOSIS (CHLAMYDIA GROUP)	2	I
	LJP - ANTISERUM, FLUORESCENT, CHLAMYDIA TRACHOMATIS	2	I
	MGM - C. TRACHOMATIS (CHLAMYDIA GROUP)	2	I
	MKZ - DNA PROBE, NUCLEIC ACID AMPLIFICATION, CHLAMYDIA	3	I
	LSK - DNA-REAGENTS, CHLAMYDIA	2	I
	LJC - ENZYME LINKED IMMUNOABSORBENT ASSAY, (CHLAMYDIAE GROUP)	2	I
66.3140	CORYNEBACTERIUM SPP. SEROLOGICAL REAGENTS		
	KLH - ANTISERA, C. ACNES	2	I
	GOP - ANTISERA, C. ACNES (553, 605)	2	I
	GOS - ANTISERUM, FLUORESCENT, C. DIPHTHERIAE	2	I
	KFI - STRIP, VIRULENCE, CORYNEBACTERIUM DIPHTHERIAE	2	I
66.3145	COXSACKIEVIRUS SEROLOGICAL REAGENTS		
	GNG - ANTIGENS, CF (INCLUDING CF CONTROL), COXSACKIEVIRUS A 1-24, B 1-6	2	I
	GNO - ANTISERA, CF, COXSACKIEVIRUS A 1-24, B 1-6	2	I
	GNM - ANTISERA, FLUORESCENT, COXSACKIEVIRUS A 1-24, B 1-6	2	I
	GNN - ANTISERA, NEUTRALIZATION, COXSACKIEVIRUS A 1-24, B 1-6	2	I
66.3200	ECHINOCOCCUS SPP. SEROLOGICAL REAGENTS		
	GPF - ANTIGEN, AGGLUTINATING, ECHINOCOCCUS SPP.	2	I
	GPD - ANTIGEN, INDIRECT FLUORESCENT ANTIBODY TEST, ECHINOCOCCUS GRANULOSUS	2	I
	GPE - ANTISERA, POSITIVE CONTROL, ECHINOCOCCUS SPP.	2	I
	MDJ - REAGENTS, CYSTICERCOSIS	2	I
66.3235	EPSTEIN-BARR VIRUS SEROLOGICAL REAGENTS		
	LJN - ANTIBODY IGM, IF, EPSTEIN-BARR VIRUS	2	I
	GNQ - ANTIGEN, CF (INCLUDING CF CONTROL), EPSTEIN-BARR VIRUS	2	I
	MCD - ANTIGEN, EBV, CAPSID	2	I
	GNP - ANTISERUM, CF, EPSTEIN-BARR VIRUS	2	I
	JRY - ANTISERUM, FLUORESCENT, EPSTEIN-BARR VIRUS	2	I
	LSF - DNA-REAGENTS, EPSTEIN-BARR VIRUS	2	I
	LLM - EPSTEIN-BARR VIRUS NUCLEAR ANTIGEN TEST	2	I
	LSE - EPSTEIN-BARR VIRUS, OTHER	2	I
366.3240	EQUINE ENCEPHALEMYELITIS VIRUS SEROLOGICAL REAGENTS		
	GQD - ANTIGENS, CF (INCLUDING CF CONTROL), EQUINE ENCEPHALITIS VIRUS, EEE,	2	I
	GQC - ANTISERA, CF, EQUINE ENCEPHALITIS VIRUS, EEE, WEE	2	I
366.3355	LISTERIA SPP. SEROLOGICAL REAGENTS		
	GSI - ANTIGENS, SLIDE AND TUBE, ALL TYPES, LISTERIA MONOCYTOGENES	2	I
	GSH - ANTISERA, ALL TYPES, LISTERIA MONOCYTOGENES	2	I
	GSG - ANTISERA, FLUORESCENT, ALL TYPES, LISTERIA MONOCYTOGENES	2	I
	MCG - DNA-PROBE, AGENT, LISTERIA	2	I
366.3360	LYMPHOCYTIC CHORIOMENINGITIS VIRUS SEROLOGICAL REAGENTS		
	GQK - ANTIGEN, CF, LYMPHOCYTIC CHORIOMENINGITIS VIRUS	2	I
	GQJ - ANTISERUM, CF, LYMPHOCYTIC CHORIOMENINGITIS VIRUS	2	I
366.3370	MYCOBACTERIUM TUBERCULOSIS IMMUNOFLUORESCENT REAGENTS		

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	GRT - ANTISERUM, FLUORESCENT, MYCOBACTERIUM TUBERCULOSIS	2	I
	LQF - DNA-REAGENTS, MYCOBACTERIUM SPP.	2	I
66.3375	MYCOPLASMA SPP. SEROLOGICAL REAGENTS		
	GSB - ANTIGENS, CF, ALL, MYCOPLASMA SPP.	2	I
	GSA - ANTISERA, ALL MYCOPLASMA SPP.	2	I
	GRZ - ANTISERA, FLUORESCENT, ALL, MYCOPLASMA SPP.	2	I
	LQG - DNA-REAGENTS, MYCOPLASMA SPP.	2	I
	LJZ - ENZYME LINKED IMMUNOABSORBENT ASSAY, MYCOPLASMA SPP.	2	I
66.3380	MUMPS VIRUS SEROLOGICAL REAGENTS		
	GRC - ANTIGEN, CF (INCLUDING CF CONTROL), MUMPS VIRUS	2	I
	GQY - ANTIGEN, HA (INCLUDING HA CONTROL), MUMPS VIRUS	2	I
	GRB - ANTISERUM, CF, MUMPS VIRUS	2	I
	GRA - ANTISERUM, FLUORESCENT, MUMPS VIRUS	2	I
	GRD - ANTISERUM, HAI, MUMPS VIRUS	2	I
	GQZ - ANTISERUM, NEUTRALIZATION, MUMPS VIRUS	2	I
	LJY - ENZYME LINKED IMMUNOABSORBENT ASSAY, MUMPS VIRUS	2	I
66.3405	POLIOVIRUS SEROLOGICAL REAGENTS		
	GOH - ANTIGENS, CF (INCLUDING CF CONTROL), POLIOVIRUS 1-3	2	I
	GOG - ANTISERA, CF, POLIOVIRUS 1-3	2	I
	GOE - ANTISERA, FLUORESCENT, POLIOVIRUS 1-3	2	I
	GOF - ANTISERA, NEUTRALIZATION, POLIOVIRUS 1-3	2	I
	LIQ - ENZYME LINKED IMMUNOABSORBENT ASSAY, ROTAVIRUS	2	I
66.3480	RESPIRATORY SYNCYTIAL VIRUS SEROLOGICAL REAGENTS		
	GQG - ANTIGEN, CF (INCLUDING CF CONTROLS), RESPIRATORY SYNCYTIAL VIRUS	2	I
	GQF - ANTISERUM, NEUTRALIZATION, RESPIRATORY SYNCYTIAL VIRUS	2	I
	MCE - RESPIRATORY SYNCYTIAL VIRUS - ELISA	2	I
	LKT - RESPIRATORY SYNCYTIAL VIRUS, ANTIGEN, ANTIBODY, IFA	2	I
66.3500	RICKETTSIA SEROLOGICAL REAGENTS		
	GPS - ANTIGEN, CF, Q FEVER	2	I
	GPQ - ANTIGEN, CF, SPOTTED FEVER GROUP	2	I
	GPO - ANTIGEN, CF, TYPHUS FEVER GROUP	2	I
	GPR - ANTISERUM, CF, Q FEVER	2	I
	GPJ - ANTISERUM, FLUORESCENT, Q FEVER	2	I
	GPM - ANTISERUM, MURINE TYPHUS FEVER	2	I
	GPK - ANTISERUM, RICKETTSIALPOX	2	I
	GPP - ANTISERUM, ROCKY MOUNTAIN SPOTTED FEVER	2	I
	GPN - ANTISERUM, TYPHUS FEVER	2	I
	LSQ - REAGENT, RICKETTSIA SEROLOGICAL	2	I
66.3600	SCHISTOSOMA SPP. SEROLOGICAL REAGENTS		
	GNH - ANTIGEN, FLUORESCENT ANTIBODY TEST, SCHISTOSOMA MANSONI	2	I
66.3680	SPOROTHRIX SCHENCKII SEROLOGICAL REAGENTS		
	GMA - ANTISERA, FLUORESCENT, SPOROTHRIX SCHENEKII	2	I
66.3740	STREPTOCOCCUS SPP. SEROLOGICAL REAGENTS		
	GTY - ANTIGENS, ALL GROUPS, STREPTOCOCCUS SPP.	2	I
	GTZ - ANTISERA, ALL GROUPS, STREPTOCOCCUS SPP.	2	I
	GWC - ANTISERA, ALL TYPES, STREPTOCOCCUS PNEUMONIAE	2	I
	GTX - ANTISERA, FLUORESCENT, ALL GROUPS, STREPTOCOCCUS SPP.	2	I

TION / 0	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
	GWB - ANTISERA, FLUORESCENT, ALL TYPES, STREPTOCOCCUS PNEUMONIAE	2	I
	MDK - DNA-PROBE, REAGENTS, STREPTOCOCCAL	2	I
	MCT - DNA-PROBE, STREP PNEUMONIAE	2	I
5.3850	TRICHINELLA SPIRALIS SEROLOGICAL REAGENTS		
	GPI - ANTIGEN, BENTONITE FLOCCULATION, TRICHINELLA SPIRALIS	2	I
	GPG - ANTIGEN, LATEX AGGLUTINATION, TRICHINELLA SPIRALIS	2	I
	GPH - ANTISERUM, BENTONITE FLOCCULATION, TRICHINELLA SPIRALIS	2	I
	MDT - ELISA, TRICHINELLA SPIRALIS	2	I
6.3870	TRYPANOSOMA SPP. SEROLOGICAL REAGENTS		
	GNF - ANTIGEN, CF, T. CRUZI	2	I
	GND - ANTIGEN, IHA, T. CRUZI	2	I
	GNE - ANTIGEN, LATEX AGGLUTINATION, T. CRUZI	2	I
	MIU - ENZYME LINKED IMMUNOSORBENT ASSAY, T. CRUZI	2	I
	MIV - IMMUNOFLUORESCENT ASSAY, T. CRUZI	2	I

.TION :0	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
:.1030	ATAXIAGRAPH		
	GWW - ATAXIAGRAPH	2	I
2.1420	ELECTROENCEPHALOGRAM (EEG) SIGNAL SPECTRUM ANALYZER		
	GWS - ANALYZER, SPECTRUM, ELECTROENCEPHALOGRAM SIGNAL	2	I
2.4060	VENTRICULAR CANNULA		
	HCD - CANNULA, VENTRICULAR	2	I
2.4545	SHUNT SYSTEM IMPLANTATION INSTRUMENT		
	GYK - INSTRUMENT, SHUNT SYSTEM IMPLANTATION	2	I
2.4650	NEUROSURGICAL SUTURE NEEDLE		
	HAS - NEEDLE, NEUROSURGICAL SUTURE	2	I
:2.4750	SKULL PUNCH		
	GXJ - PUNCH, SKULL	2	I

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884.5435	UNSCENTED MENSTRUAL PAD HHD - PAD, MENSTRUAL, UNSCENTED	1	I

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36.1780	RETINOSCOPE		
	HKM - RETINOSCOPE, BATTERY-POWERED	1	I
36.1940	TONOMETER STERILIZER		
	HKZ - STERILIZER, TONOMETER	2	I
36.4070	POWERED CORNEAL BURR		
	HQS - BURR, CORNEAL, AC-POWERED	2	I
	HOG - BURR, CORNEAL, BATTERY-POWERED	2	I
	HRG - ENGINE, TREPHINE, ACCESSORIES, AC-POWERED	2	I
	HRF - ENGINE, TREPHINE, ACCESSORIES, BATTERY-POWERED	2	I
	HLD - ENGINE, TREPHINE, ACCESSORIES, GAS-POWERED	2	I
86.4300	INTRACULAR LENS GUIDE		
	KYB - LENS, GUIDE, INTRAOCULAR	2	I
86.4370	KERATOME		
	HNO - KERATOME, AC-POWERED	1	I
	HMY - KERATOME, BATTERY-POWERED	1	I
86.5850	SUNGLASSES (NON-PRESCRIPTION)		
	HQY - SUNGLASSES (NON-PRESCRIPTION INCLUDING PHOTOSENSITIVE)	1	I

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38.1500	AC-POWERED GONIOMETER		
	KQX - GONIOMETER, AC-POWERED	1	I
38.4150	CALIPERS FOR CLINICAL USE		
	KTZ - CALIPER	1	I

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64.2280	CULTURED ANIMAL AND HUMAN CELLS		
	KIR - CELLS, ANIMAL AND HUMAN, CULTURED	1	I

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)0.3850	MECHANICAL WHEELCHAIR		
	LBE - STROLLER, ADAPTIVE	2	I
	IOR - WHEELCHAIR, MECHANICAL	2	I
)0.5180	MANUAL PATIENT ROTATION BED		
	INY - BED, PATIENT ROTATION, MANUAL	2	I
)0.5710	HOT OR COLD DISPOSABLE PACK		
	IMD - PACK, HOT OR COLD, DISPOSABLE	2	I

CTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
92.1100	SCINTILLATION GAMMA CAMERA		
	IYX - CAMERA, SCINTILLATION (GAMMA)	2	I
92.1110	POSITRON CAMERA		
	IZC - CAMERA, POSITRON	2	I
92.1300	NUCLEAR RECTILINEAR SCANNER		
	IYW - SCANNER, RECTILINEAR, NUCLEAR	1	I
92.1320	NUCLEAR UPTAKE PROBE		
	IZD - PROBE, UPTAKE, NUCLEAR	1	I
92.1330	NUCLEAR WHOLE BODY SCANNER		
	JAM - SCANNER, WHOLE BODY, NUCLEAR	1	I
92.1410	NUCLEAR ELECTROCARDIOGRAPH SYNCHRONIZER		
	IYY - SYNCHRONIZER, ELECTROCARDIOGRAPH, NUCLEAR	1	I
92.1890	RADIOGRAPHIC-FILM ILLUMINATOR		
	IXC - ILLUMINATOR, RADIOGRAPHIC-FILM	1	I
	JAG - ILLUMINATOR, RADIOGRAPHIC-FILM, EXPLOSION-PROOF	1	I
92.1910	RADIOGRAPHIC GRID		
	IXJ - GRID, RADIOGRAPHIC	1	I
92.1960	RADIOGRAPHIC INTENSIFYING SCREEN		
	EAM - SCREEN, INTENSIFYING, RADIOGRAPHIC	2	I
92.1970	RADIOGRAPHIC ECG/RESPIRATOR SYNCHRONIZER		
	IXO - SYNCHRONIZER, ECG/RESPIRATOR, RADIOGRAPHIC	1	I
92.5650	MANUAL RADIONUCLIDE APPLICATOR SYSTEM		
	IWJ - SYSTEM, APPLICATOR, RADIONUCLIDE, MANUAL	2	I

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8.4200	INTRODUCTION/DRAINAGE CATHETER AND ACCESSORIES		
	KGZ - ACCESSORIES, CATHETER	2	I
	GCE - ADAPTOR, CATHETER	2	I
	FGY - CANNULA, INJECTION	2	I
	GBA - CATHETER, BALLOON TYPE	2	I
	GBZ - CATHETER, CHOLANGIOGRAPHY	2	I
	GBQ - CATHETER, CONTINUOUS IRRIGATION	2	I
	GBY - CATHETER, EUSTACHIAN, GENERAL & PLASTIC SURGERY	2	I
	JCY - CATHETER, INFUSION	2	I
	GBX - CATHETER, IRRIGATION	2	I
	GBP - CATHETER, MULTIPLE LUMEN	2	I
	GBO - CATHETER, NEPHROSTOMY, GENERAL & PLASTIC SURGERY	2	I
	GBN - CATHETER, PEDIATRIC, GENERAL & PLASTIC SURGERY	2	I
	GBW - CATHETER, PERITONEAL	2	I
	GBS - CATHETER, VENTRICULAR, GENERAL & PLASTIC SURGERY	2	I
	GCD - CONNECTOR, CATHETER	2	I
	GCC - DILATOR, CATHETER	2	I
	GCB - NEEDLE, CATHETER	2	I
78.4320	REMOVABLE SKIN CLIP		
	FZQ - CLIP, REMOVABLE (SKIN)	2	I
78.4460	SURGEON'S GLOVES		
	KGO - SURGEON'S GLOVES	1	I
78.4680	NONPOWERED, SINGLE PATIENT, PORTABLE SUCTION APPARATUS		
	GCY - APPARATUS, SUCTION, SINGLE PATIENT USE, PORTABLE, NONPOWERED	2	I
78.4760	REMOVABLE SKIN STAPLE		
	GDT - STAPLE, REMOVABLE (SKIN)	2	I
78.4820	AC-POWERED, BATTERY-POWERED, AND PNEUMATICALLY POWERED SURGICAL INSTRUMENT MOTOR		
	GFG - BIT, SURGICAL	2	I
	GFA - BLADE, SAW, GENERAL & PLASTIC SURGERY, SURGICAL	2	I
	DWH - BLADE, SAW, SURGICAL, CARDIOVASCULAR	2	I
	BTX - BOARD, ARM (WITH COVER)	2	I
	GFE - BRUSH, DERMABRASION	1	I
	GFF - BUR, SURGICAL, GENERAL & PLASTIC SURGERY	2	I
	KDG - CHISEL (OSTEOTOME)	2	I
	GFD - DERMATOME	2	I
	GFC - DRIVER, SURGICAL, PIN	2	I
	GFB - HEAD, SURGICAL, HAMMER	2	I
	GEY - MOTOR, SURGICAL INSTRUMENT, AC-POWERED	2	I
	GET - MOTOR, SURGICAL INSTRUMENT, PNEUMATIC POWERED	2	I
	DWI - SAW, ELECTRICALLY POWERED	2	I
	KFK - SAW, PNEUMATICALLY POWERED	2	I
	HAB - SAW, POWERED, AND ACCESSORIES	2	I
378.4960	AIR OR AC-POWERED OPERATING TABLE AND AIR OR AC-POWERED OPERATING CHAIR & ACCESS		
	GBB - CHAIR, SURGICAL, AC-POWERED	2	I
	FQO - TABLE, OPERATING-ROOM, AC-POWERED	2	I
	GDC - TABLE, OPERATING-ROOM, ELECTRICAL	2	I
	FWW - TABLE, OPERATING-ROOM, PNEUMATIC	2	I

SECTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
	JEA - TABLE, SURGICAL WITH ORTHOPEDIC ACCESSORIES, AC-POWERED	2	I
80.5090	LIQUID BANDAGE		
	KMF - BANDAGE, LIQUID	2	I

SECTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
862.2230	CHROMATOGRAPHIC SEPARATION MATERIAL FOR CLINICAL USE		
	DKO - ADSORBENTS, ION-EXCHANGE	1	I
	DJY - ION-EXCHANGE CHROMATOGRAPHY	1	I
	DMG - PAPERS, ION	1	I
	KEA - RESINS, ION-EXCHANGE	1	I
862.2250	GAS LIQUID CHROMATOGRAPHY SYSTEM FOR CLINICAL USE		
	JSQ - CHROMATOGRAPHY FOR BACTERIAL IDENTIFICATION	2	I
	KZQ - CHROMATOGRAPHY(GAS), CLINICAL USE	2	I
	DLG - COATING, LIQUID, GLC	2	I
	DJA - COLUMN SUPPORTS, GLC	2	I
	DII - COLUMNS, GLC	2	I
	DMS - GASES, GLC	2	I
862.2260	HIGH PRESSURE LIQUID CHROMATOGRAPHY SYSTEM FOR CLINICAL USE		
	KIE - APPARATUS, HIGH PRESSURE LIQUID CHROMATOGRAPHY	2	I
	KZR - CHROMATOGRAPHY (LIQUID, GEL), CLINICAL USE	2	I
	DPM - COLUMNS, LIQUID CHROMATOGRAPHY	2	I
	LEQ - DETECTORS, ELECTROCHEMICAL, LIQUID CHROMATOGRAPHY	2	I
	LDM - INSTRUMENTATION, HIGH PRESSURE LIQUID CHROMATOGRAPHY	2	I
	DMZ - LIQUID CHROMATOGRAPHY, ADSORBENT	2	I
	DNH - RESINS, ION-EXCHANGE, LIQUID CHROMATOGRAPHY	2	I
862.2270	THIN-LAYER CHROMATOGRAPHY SYSTEM FOR CLINICAL USE		
	DPA - APPARATUS, GENERAL USE, THIN LAYER CHROMATOGRAPHY	1	I
	DLC - ATOMIZER, TLC	1	I
	KZS - CHROMATOGRAPHY (THIN LAYER), CLINICAL USE	1	I
	DKY - INDICATOR, ALUMINA FLUORESCENT, TLC	1	I
	DJO - INDICATOR, CELLULOSE FLUORESCENT, TLC	1	I
	DLO - INDICATOR, SILICA GEL FLUORESCENT, TLC	1	I
	DLY - PLATE, ALUMINA, TLC	1	I
	DKG - PLATE, CELLULOSE, TLC	1	I
	DKS - PLATE, SILICA GEL, TLC	1	I
	DKK - TANKS, DEVELOPING, TLC	1	I
	DJS - U.V. LIGHT, TLC	1	I
862.2850	ATOMIC ABSORPTION SPECTROPHOTOMETER FOR CLINICAL USE		
	JXR - ATOMIC ABSORPTION SPECTROPHOTOMETER, GENERAL USE	2	I
862.2860	MASS SPECTROMETER FOR CLINICAL USE		
	DOP - MASS SPECTROMETER, CLINICAL USE	2	I
862.3050	BREATH-ALCOHOL TEST SYSTEM		
	DJZ - DEVICES, BREATH TRAPPING, ALCOHOL	2	I
862.3110	ANTIMONY TEST SYSTEM		
	DNE - ATOMIC ABSORPTION, ANTIMONY	2	I
862.3120	ARSENIC TEST SYSTEM		
	DNZ - ATOMIC ABSORPTION, ARSENIC	2	I
862.3220	CARBON MONOXIDE TEST SYSTEM		
	JKT - GAS CHROMATOGRAPH, CARBON-MONOXIDE	2	I
	JKS - SPECTRAL ABSORB. CURVE, OXYHEMOGLOBIN, CARBOXYHEMOGLOBIN,	2	I
862.3240	CHOLINESTERASE TEST SYSTEM		
	DLI - ACETYLCHOLINE CHLORIDE, SPECIFIC REAGENT FOR PSEUDO CHOLINESTERASE	2	I

ECTION NO	- REGULATION NAME PRODUCT CODE - DEVICE NAME	TIER	CLASS
	DIG - CHOLINESTERASE TEST PAPER	2	I
	DIH - COLORIMETRY, CHOLINESTERASE	2	I
	DOH - ELECTROMETRY, CHOLINESTERASE	2	I
	DMR - SOLUTION, M-NITROPHENOL, SPECIFIC REAGENT FOR CHOLINESTERASE	2	I
362.3280	CLINICAL TOXICOLOGY CONTROL MATERIAL		
	DKC - ALCOHOL CONTROL MATERIALS	2	I
	DJK - DIGITOXIN CONTROL SERUM, RIA	2	I
	DMP - DIGOXIN CONTROL SERUM, RIA	2	I
	DIF - DRUG MIXTURE CONTROL MATERIALS	2	I
	LAS - DRUG SPECIFIC CONTROL MATERIALS	2	I
	DIE - HEAVY METALS CONTROL MATERIALS	2	I
	LAX - LIDOCAINE CONTROL MATERIALS	2	I
	LAY - METHOTREXATE CONTROL MATERIALS	2	I
	LAZ - N-ACETYLPROCAINAMIDE CONTROL MATERIALS	2	I
	LBA - PROCAINAMIDE CONTROL MATERIALS	2	I
	LAW - THEOPHYLLINE CONTROL MATERIALS	2	I
362.3600	MERCURY TEST SYSTEM		
	DPH - MERCURY, ATOMIC ABSORPTION	2	I

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DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

IDE Memorandum - #D95-1

Date · JUL 12 1995

From Office of Device Evaluation (HFZ-400)

Subject Goals and Initiatives for the IDE Program

To ODE Review Staff

Purpose

The purpose of this memorandum is to establish procedures for the efficient review of IDEs and to identify performance goals for the IDE Program.

Background

The Office of Device Evaluation (ODE) has traditionally approved approximately one third of the original investigational device exemption (IDE) applications in the first 30 day review cycle. In recent times (fiscal years (FY) 1993 and 1994), however, only 25% of the original IDE applications were approved during this initial review period. In addition, the average total time from receipt of the application to approval increased to 242 days after averaging 178 days for the last 5 years.

The reasons for non-approval may be summarized as relating to inadequate characterization of the device being investigated, poorly designed clinical trials, and inadequate subject protection measures. In all cases, ODE's intent has been to improve the quality of the information derived from the investigations and to protect the well-being of those participating in the clinical trials. We must recognize, however, that our approach has had some unintended effects such as discouraging the conduct of the clinical trials and thus the generation of potentially useful information or causing the trials to be conducted outside the United States without guidance from FDA. ODE staff has also been expending considerable resources in reviewing multiple amendments over an extended period of time.

If the performance goals presented below are achieved, the gain to be realized by both the regulated industry and ODE staff would be significant. Increasing the approval rate and reducing the time to approval for original IDEs to more reasonable levels will encourage the medical device industry to conduct their clinical investigations in the

United States (U.S.) rather than overseas. If the clinical trials are conducted domestically, and thus with FDA guidance, the quality of the trials and the data generated from them should be more congruent with premarket approval requirements than if the investigations were conducted overseas without input from FDA review. In addition, the data resulting from the domestic trials will be representative of medical practice in the U.S. Thus, the review process for the marketing applications should proceed more expeditiously, saving time and resources for the regulated industry and FDA. Finally, if the device trials are conducted here, U.S. physicians will have earlier access to and experience with these new technologies, while U.S. patients participating in the trials will also have the potential benefit of these novel therapies.

Below, the performance goals for the IDE Program and the initiatives to be implemented to help reach these goals are presented.

1) During FY95, increase the approval rate for original IDEs from its current rate of 27% (FY94) to approximately 66% in the first 30 day review cycle, especially for those submissions for which there was FDA-Industry interaction during the process (e.g., pre-IDE meetings, submissions, etc.).

2) During FY95, reduce the average number of review cycles to approval to less than two cycles. Currently, more than two amendments per IDE are required before approval of the application. Thus, at least three review cycles are generally required before the initiation of a device clinical trial.

Procedures

In order to help ODE's reviewing divisions reach these performance goals, the following initiatives will be implemented.

1) **Pre-IDE meetings.** Sponsors should be encouraged to meet with ODE staff before the IDE application is submitted for review. Meeting with the regulated industry before the IDE application is submitted should serve to increase the sponsor's understanding of various FDA requirements, regulations, and guidance documents and thus lead to more complete original IDE applications. (See attached policy entitled, "Procedures for Pre-IDE Meetings and Submissions.")

2) **Pre-IDE applications.** Sponsors should be encouraged to submit preliminary information for ODE review before making the formal IDE submission. Sponsors should submit those sections of the IDE application for which they require FDA guidance (e.g., clinical protocol design, pre-clinical testing, etc.) while preparing the remainder of the IDE submission. This will allow ODE staff to provide informal guidance to the industry on troublesome parts of the IDE application before the official submission is made. In addition, since this informal review will be conducted while other parts of the application are being prepared, it should not extend the total preparation time for the IDE application. (See attached policy entitled, "Procedures for Pre-IDE Meetings and Submissions.")

3) An interactive review process. By communicating frequently with industry during the review process, rather than only at the completion of the review, deficient information can be addressed within fewer review cycles. This would be of significant benefit to both industry and ODE staff. ODE reviewers, with the concurrence of their supervisors, should feel free to use the telephone or telefacsimile to aid in the interactive review. Documentation of this communication must be included in the IDE record, and hardcopies of information transmitted by telefacsimile must be logged into the IDE database. (See attached policy entitled,"IDE Telefacsimile Policy.")

4) Use of new strategies in the clinical development of devices. If the original IDE application does not support the initiation of the substantive (pivotal) clinical trial, ODE staff should consider the use of feasibility/pilot studies. Such trials may be used to: provide investigators with initial device experience; help address specific safety concerns; permit initial assessment of device design; better define the clinical endpoints, success/failure criteria, the intended patient population, and appropriate follow-up period; assess the therapeutic effect of the device and estimate the required patient population size; and clarify the possible medical claims before the multi-centered trial is initiated. The type of device, the risks posed by the device, what is known about these risks, and the questions to be addressed in the limited study must all be considered when deciding whether a feasibility/pilot study is appropriate, and if so, the size of the study. Thus, the use of this type of strategy in the conduct of clinical trials not only permits a trial which may have otherwise been disapproved to be initiated on a limited basis but also provides for a better designed substantive trial for the marketing application.

Effective Date

This memorandum is effective immediately.

Susan Alpert, Ph.D., M.D.

PROCEDURES FOR

PRE-IDE MEETINGS AND SUBMISSIONS

In order to facilitate the initiation of clinical trials under the Investigational Device Exemptions (IDE) regulations, FDA is encouraging sponsors to begin communicating with the reviewing division prior to the submission of the original IDE application. This communication may take the form of a "Pre-IDE" meeting and/or a Pre-IDE submission. Pre-IDE meetings should occur early in the IDE preparation process so that any advice/guidance provided by ODE staff can be used in the development of supporting pre-clinical data or incorporated into the IDE application. These meetings may take the form of telephone conference calls, video conferences, or face-to-face discussions. In addition to the general requirements set forth in Blue Book Memorandum #I89-3, "Meetings with the Regulated Industry," and #I93-1, "Telephone Communications Between ODE Staff and Manufacturers," the following requirements apply specifically to the IDE program. All pre-IDE meetings should be recorded by the division and reported on a quarterly basis to senior ODE management. Minutes of the meeting should include the date of the meeting, the attendees (FDA and industry), whether material was submitted prior to the meeting for discussion/review by ODE staff, a summary of the discussion, and any recommendations or guidance provided by FDA.

Pre-IDE submissions may consist of a draft clinical protocol, a proposal for pre-clinical testing, pre-clinical test results, or other information for which the sponsor wishes to obtain preliminary FDA review and comment in order to facilitate the IDE application process. Pre-IDE submissions may also consist of protocols for foreign studies when the studies will be used to support future marketing applications to be submitted to FDA.

Pre-IDE submissions will receive the same confidentiality of data and information as provided for IDE applications under 21 CFR 812.38. Therefore, FDA will not disclose the existence of a pre-IDE submission unless its existence has previously been publicly disclosed or acknowledged, until FDA approves an application for marketing approval of the device subject to this submission.

Pre-IDE submissions must be recorded and tracked, and so should be submitted in triplicate to the Document Mail Center (DMC) for processing. The DMC will assign the document a Pre-IDE number (PIDE), record it in the Pre-IDE logbook, and forward it to the appropriate division for review. (At this time, the IDE database cannot track Pre-IDE submissions.) If a Pre-IDE submission is received by the division without going through the DMC, the division is responsible for taking the document to the DMC so that it can be properly processed. At the time of log-in, the document mail clerk will also record the dates of submission and receipt, the sponsor's name, the name of the device, and the division to which it is assigned. The Pre-IDE number will be recorded on the top right corner of the submission, just as is done for official IDE applications.

Since the IDE database base cannot track Pre-IDEs, the divisions will be responsible for tracking the submissions and ensuring that a timely

response is issued. A Pre-IDE boilerplate acknowledgment letter is available on the LAN (P-01) and should be sent to the sponsor upon receipt of the Pre-IDE submission. This letter indicates that FDA will attempt to provide a response to the sponsor in a timely manner, usually within 60 days of receipt. ODE's response may take the form of a written letter, or comments may be provided in a meeting or during a telephone conference call. Whichever method of response is used, it should be documented in the Pre-IDE file. (A copy of the letter, meeting minutes, or memorandum of the telephone conversation should be securely attached to the Pre-IDE submission.) There is a shelf in DMC where Pre-IDE submissions may be stored.

When the original IDE application is submitted, the division must note in the comments section of the IDE Tracking Sheets the Pre-IDE number assigned by the DMC if a Pre-IDE had been reviewed for this submission. This will allow a method of connecting the Pre-IDE to the original IDE application.

IDE TELEFACSIMILE POLICY

General guidance for the acceptance of telefacsimile (FAX) telecommunications is provided in ODE's Blue Book Memorandum #I90-3 "Document Control Procedures." In this memorandum, it is stated that "As a general rule, information and data required to review and reach a decision on a submission may not be accepted via fax." In addition, according to the IDE regulations (21 CFR 812.20(a)(3)), all correspondence concerning an application or a supplemental application must be submitted by registered mail or by hand. The intent of this section of the regulations was to ensure that in order for information to be considered an official part of the IDE file, that information must be submitted in writing. At the time the IDE regulations were developed, however, the technology which permits communication via telefacsimile did not exist. Therefore, ODE has requested an official ruling from the Office of General Counsel on the acceptability of FAXed information, i.e., the need for a follow-up hardcopy. Until a definitive response is received, the policy presented below will serve as the official IDE FAX policy for the Office.

As stated above, past Office policy regarding use of FAXed information, as outlined in Blue Book Memorandum #I90-3 and as amplified in a February 17, 1994 memorandum by ODE's Integrity Officer, dictated that FAXed information could be used for purposes such as to facilitate the exchange of ideas and clarify points of discussion but could not serve as the basis of a decision without a confirmatory hardcopy. While the above policy statements remain in effect, ODE is encouraging more liberal use of the FAX machine as an aid to resolving deficiencies in the IDE application. Thus, a sponsor could submit information addressing deficiencies in areas such as the pre-clinical testing, the investigational plan, the risk analysis, the informed consent document, manufacturing procedures, etc., which had previously been discussed by phone with the reviewer. Although a follow-up hardcopy of the FAXed information still needs to be added to the administrative record and thus must be submitted to the Document Mail Center (DMC), early receipt of the information by FAX should permit a more expeditious review of the information and resolution of the deficiencies.

A follow-up hardcopy of the FAXed information should be received in the DMC by the 30th day of the review cycle so that it can be properly logged in as an IDE amendment. Therefore, reviewers must notify the sponsor that any information which is FAXed to ODE must also be sent in triplicate by overnight mail to the DMC for receipt by the next business day. If multiple FAXes are received by the division during the course of the review, hardcopies of all of the information may be submitted in one mailing rather than after each individual FAX. When the follow-up hardcopies are received by the DMC, one copy will be added to Copy 1 of the IDE file and one copy will be forwarded to the division for verification that the hardcopy is in fact a duplicate of the FAXed information. The hardcopy and a note stating that the hardcopy is a duplicate of the previously received FAX should be added to the file by the reviewer. The third copy of the hardcopy is the reviewer's deskcopy and can be added to Copy 3 of the IDE file or discarded.

If the follow-up hardcopy is expected to arrive after day 30, reviewers must FAX the Duplicate Information Sheet (see attachment) to the sponsor. This sheet is to be used as a cover sheet to the hardcopy to ensure that when the information is received by the DMC, it will be correctly logged in as an IDE amendment to the original IDE application rather than as a supplement. Subsequent processing of the hardcopy will be as above.

FAX

DUPLICATE

IDE Number: _____

I certify that the information contained in this submission is an exact duplicate of information which was previously provided by telefacsimile on the date(s) listed below. (That is, no new information which has not been previously provided is contained in this submission.)

Submitted by: _____ _____
(Name) (Signature and date)

_____
(Title)

_____
(Company Name)

_____
(Street Address)

_____
(City, State and Zip Code)

_____
(Phone Number)

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the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 15, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-4067 Filed 2-22-96; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 95N-0357]

Medical Devices; Investigational Devices; Interagency Agreement Between the Food and Drug Administration and the Health Care Financing Administration; Categorization of Investigational Devices for Coverage under Medicare; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of an interagency agreement between FDA and the Health Care Financing Administration (HCFA) and a list of all FDA-approved investigational device exemptions (IDE's) and their corresponding categorization determinations for possible Medicare reimbursement. This list was compiled in accordance with the categorization criteria set forth in the interagency agreement. The HCFA/FDA interagency agreement regarding investigational devices describes procedures by which FDA will assist HCFA in identifying nonexperimental/investigational devices that are potentially covered by Medicare under a final rule recently issued by HCFA extending coverage to certain devices and related services. FDA is making the interagency agreement and the list of FDA-approved IDE's and their categorization determinations available to IDE sponsors and the public.

DATES: The HCFA final rule "Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services" became effective on November 1, 1995. The HCFA/FDA interagency agreement became effective on September 8, 1995.

ADDRESSES: Submit written requests for a copy of the interagency agreement and the categorization list to the Division of Small Manufacturers Assistance (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your request. Copies of the interagency agreement and the categorization list are available for public examination in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857 between 9 a.m. and 4 p.m., Monday through Friday. Copies of a facsimile of this information are available from the Center for Devices and Radiological Health's (CDRH's) Facts on Demand (1-800-899-0381). This information may also be obtained from the electronic docket adminis d by the Division of Small Manufactu Assistance and is available to anyone with a video terminal or personal computer (1-800-252-1366, 1-800-222-0185, or 1-301-594-2741). Requests for reconsideration of the categorization of an IDE should be submitted in the same manner as an IDE supplement and should reference the IDE number, and be submitted in triplicate to: IDE Document Mail Center (HFZ-401), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: John Ensign, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 19, 1995 (60 FR 48417), HCFA published a final rule in which it announced that it would consider for Medicare coverage certain devices with an FDA-approved IDE that have been categorized as nonexperimental/investigational. An FDA-approved IDE application permits a device which otherwise could not be lawfully shipped without marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) and 21 CFR parts 812 and 813.

Under section 513 of the act (21 U.S.C. 360c), all devices must be classified into one of three regulatory classes: Class I (general controls), C II (special controls), or Class III (premarket approval). For the purposes of consideration for reimbursement under the Medicare program and in accordance with the procedures set forth in the HCFA final rule published on September 19, 1995, FDA has categorized all FDA-approved IDE's into either Category A (experimental/investigational) or Category B (nonexperimental/investigational). An experimental/investigational (Category A) device refers to an innovative device believed to be in Class III for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved, and the FDA is unsure whether the device type can be safe and effective). A nonexperimental/investigational (Category B) device refers to a device believed to be in Class I or Class II, or a device believed to be

in Class III for which the incremental risk is the primary risk in question (that is, underlying questions of safety and effectiveness of the device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. The specific criteria used to categorize the IDE's are set forth in Attachment A of the HCFA/FDA interagency agreement. In order to facilitate the processing of Medicare claims, FDA and HCFA encourage IDE sponsors to provide the IDE application numbers to the hospitals and clinical investigators participating in the sponsors' clinical investigations.

According to the September 19, 1995, HCFA final rule, IDE's which have been placed in Category B by FDA would be eligible for Medicare coverage consideration. The final coverage decision, however, will encompass other factors and thus will be made by HCFA.

By this notice, FDA is making available a list of all FDA-approved IDE's, the corresponding categorization determination (Category A or Category B), and the rationale for the determination. FDA will update this list as circumstances require and will make the revised list available through the electronic docket and Facts on Demand (details above), and in the Dockets Management Branch (address above). As set forth in the September 19, 1995, final rule, an IDE sponsor may seek reconsideration of a categorization determination by submitting a request for re-evaluation to FDA. Requests for re-evaluation should be submitted in the same manner as an IDE supplement to the IDE Document Mail Center (address above). IDE sponsors may submit this request for re-evaluation at any time, i.e., there is no time limit for submitting a reconsideration request to FDA. Further information about categorization, its effect on Medicare reimbursement, and appeal of a categorization determination, is contained in the September 19, 1995, final rule cited above.

Dated: February 12, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health

[FR Doc. 96–4066 Filed 2–22–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Submitted for Collection of Public Comment: Submission for OMB Review

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and the Clinical Laboratory Improvement Act (CLIA) Exemption Under State Laboratory Programs; *Form No.:* HCFA R–185; *Use:* The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation/licensure process is equal to or more stringent than those of CLIA; *Frequency:* Other (initial application/as needed); *Affected Public:* Not-for-profit institutions, State, local, or tribal government.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 24, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 96–4105 Filed 2–22–96; 8:45 am]

BILLING CODE 4120–03–P

Submitted for Collection of Public Comment: Submission for OMB Review

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension; *Title of Information Collection:* Sole Community Home Health Agencies (HHA) at 42 CFR424.22(b)(2), (f) and (g); *Form No.:* HCFA R–85; *Use:* These regulations implement the rules for participation of HHAs in Medicare and the establishment and review of plans of care for home health services. These regulations make it easier for certain HHAs to meet certification and plan of care requirements. *Frequency:* Annually; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 20; *Total Annual Hours:* 40.

To request copies of the proposed paperwork collections referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated at the following address: OMB Human Resources and Housing Branch,

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Reproductive, Abdominal, Ear Nose & Throat, and Radiological Devices

PANEL TRACK PMA SUPPLEMENT

Document Number: Panel:
Trade Name:
Generic Name:
PMA Sponsor:

		Planned			Actual	
Event	Reviewer	Elap Days	Starting Date	Ending Date	Ending Date	Elap Days
Date Supplement Recieved CDRH					01/01/00	
Date Supplement Recieved DRAERD					01/01/00	
Date Supplement Recieved (Branch)					01/01/00	
Date Supplement Recieved Reviewer					01/01/00	
SCIENTIFIC REVIEW						
Clinical Review #1		95	01/01/00	04/05/00		
Clinical Review #2		95	01/01/00	04/05/00		
Engineering/Physics Review		95	01/01/00	04/05/00		
Chemistry/Biomaterial Review		95	01/01/00	04/05/00		
Biological/Sterility Review		95	01/01/00	04/05/00		
Toxicology/Biocompatibility Review		95	01/01/00	04/05/00		
Statistics Review		95	01/01/00	04/05/00		
Labelling Review		95	01/01/00	04/05/00		
Other Review		95	01/01/00	04/05/00		
Reviewer's Recomm/Proposed SSED Due		10	04/05/00	04/15/00		
DRAERD Mgmt Rev/Edit Recommend		10	04/15/00	04/25/00		
Draft SSED to ODE Director & PMA Staff		10	04/22/00	05/02/00		
Office Director PMA Meeting				05/09/00		
PANEL MEETING						
BC & Reviewer Schedule Panel Meeting				03/01/00		
Draft Panel Mtng FR Notice to Cmte Mgmt				03/21/00		
Notify sponsor it is going to Panel				03/31/00		
Final Panel Mtng FR Notice to Cmte Mgmt				03/31/00		
Prep documents for Distribution to Panel				05/02/00		
Identify questions for Panel				05/09/00		
Office Director PMA Meeting				05/09/00		
Comm issues with firm going to Panel				05/16/00		
Panel Meeting				05/30/00		
"24 Hour" Panel Highlights				05/31/00		
Draft Approval Package				06/13/00		
(Decision) Letter to POS				06/29/00		
POS Logout						

Prepared: 04/24/96

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Reproductive, Abdominal, Ear Nose & Throat
and Radiological Devices

NO PANEL TRACK PMA SUPPLEMENT

DOCUMENT NUMBER: P
TRADE NAME:
GENERIC NAME:
PMA SPONSOR:

		Planned			Actual	
Event	Reviewer	Elap Days	Starting Date	Ending Date	Ending Date	Elap Days
Date Supplement Received CDRH					02/28/95	
Date Supplement Received DRAERD					02/28/95	
Date Supplement Received (Branch)					02/28/95	
Date Supplement Received Reviewer					03/03/95	3
SCIENTIFIC REVIEW						
Clinical Review #1		127	03/03/95	07/08/95		
Clinical Review #2		127	03/03/95	07/08/95		
Engineering/Physics Review		127	03/03/95	07/08/95		
Chemistry/Biomaterial Review		127	03/03/95	07/08/95		
Biological/Sterility Review		127	03/03/95	07/08/95		
Toxicology/Biocompatibility Review		127	03/03/95	07/08/95		
Statistics Review		127	03/03/95	07/08/95		
Labelling Review		127	03/03/95	07/08/95		
Other Review		127	03/03/95	07/08/95		
Reviewer's Recomm/Proposed SSED Due		10	07/08/95	07/18/95		
Branch Chief's Review & Edit		10	07/18/95	07/28/95		
Associate Director's Review & Edit		10	07/28/95	08/07/95		
Division Director's Review & Edit		10	08/07/95	08/17/95		
(Decision) Letter to POS		10	08/17/95	08/27/95		
POS Logout						

Prepared: 04/24/96

DRAERD PANEL TRACK PMA ORIGINAL MANAGEMENT SHEET

Prepared: 04/24/96

Document Number: P960000
Trade Name:
Generic Name:
PMA Sponsor:

		Planned			Actual	
Event	Reviewer	Elap. Days	Starting Date	Ending Date	Ending Date	Elap. Days
PMA Received CDRH					01/01/00	
PMA Received DRAERD					01/01/00	
PMA Received (Branch)					01/01/00	
PMA Received Reviewer					01/01/00	
FILING REVIEW						
Administrative Review		30	01/01/00	01/31/00	01/31/00	30
Clinical Review #1		30	01/01/00	01/31/00	01/31/00	30
Clinical Review #2		30	01/01/00	01/31/00	01/31/00	30
Engr/Phys Review		30	01/01/00	01/31/00	01/31/00	30
Chem/Biomat'l Review		30	01/01/00	01/31/00	01/31/00	30
Biological/Sterility Review		30	01/01/00	01/31/00	01/31/00	30
Tox/Biocompat Review		30	01/01/00	01/31/00	01/31/00	30
Statistics Review		30	01/01/00	01/31/00	01/31/00	30
Labelling Review		30	01/01/00	01/31/00	01/31/00	30
Other Review		30	01/01/00	01/31/00	01/31/00	30
Filing Meeting		30		01/31/00	01/31/00	30
(Filing Decision) Letter to POS		38		02/08/00	02/08/00	38
(Filing Decision) Letter Dated		45		02/15/00	02/15/00	45
GMP & BIMO Requested						
SCIENTIFIC REVIEW						
Panel Decision Date				03/01/00	03/01/00	60
Administrative Review		82	01/31/00	04/22/00	04/22/00	112
Clinical Review #1		82	01/31/00	04/22/00	04/22/00	112
Clinical Review #2		82	01/31/00	04/22/00	04/22/00	112
Engineering/Physics Review		82	01/31/00	04/22/00	04/22/00	112
Chemistry/Biomaterial Review		82	01/31/00	04/22/00	04/22/00	112
Biological/Sterility Review		82	01/31/00	04/22/00	04/22/00	112
Tox/Biocompatability Review		82	01/31/00	04/22/00	04/22/00	112
Statistics Review		82	01/31/00	04/22/00	04/22/00	112
Labelling Review		82	01/31/00	04/22/00	04/22/00	112
Other Review		82	01/31/00	04/22/00	04/22/00	112
Draft Pkg Prepared & Edited		10	04/22/00	05/02/00	05/02/00	122
Draft Pkg to ODE Dir & PMA Staff				05/02/00	05/02/00	122
Office Director PMA Meeting				05/09/00	05/09/00	129
PANEL MEETING						
Draft FR Notice to Comte Mgmt				03/21/00	03/21/00	80
Notify sponsor of Panel				03/31/00	03/31/00	90
Final FR Notice to Comte Mgmt				03/31/00	03/31/00	90
Prep & distr documents to Panel				05/02/00	05/02/00	122
Identify questions for Panel				05/09/00	05/09/00	129
Office Director PMA Meeting				05/09/00	05/09/00	129
Communicate issues to sponsor				05/16/00	05/16/00	136
Panel Meeting				05/30/00	05/30/00	150
"24 Hour" Panel Highlights				05/31/00	05/31/00	151
Draft (Decision) Ltr/Pkg to POS				06/09/00	06/09/00	160
Final (Decision) Ltr/Pkg to POS				06/19/00	06/19/00	170
Final (Decision) Ltr/Pkg Dated				06/29/00	06/29/00	180

DRAERD NO PANEL TRACK ORIGINAL PMA MANAGEMENT SHEET

Document Number: P
Trade Name:
Generic Name:
PMA Sponsor:

		Planned			Actual	
Event	Reviewer	Elap. Days	Starting Date	Ending Date	Ending Date	Elap. Days
PMA Received CDRH					01/01/00	
PMA Received DRAERD					01/01/00	
PMA Received BRANCH					01/01/00	
PMA Received Reviewer					01/01/00	
FILING REVIEW						
Administrative Review		30	01/01/00	01/31/00		
Clinical Review #1		30	01/01/00	01/31/00		
Clinical Review #2		30	01/01/00	01/31/00		
Engineering/Physics Review		30	01/01/00	01/31/00		
Chemistry/Biomaterial Review		30	01/01/00	01/31/00		
Biological/Sterility Review		30	01/01/00	01/31/00		
Toxicology/Biocompatibility Review		30	01/01/00	01/31/00		
Statistics Review		30	01/01/00	01/31/00		
Labelling Review		30	01/01/00	01/31/00		
Other Review		30	01/01/00	01/31/00		
Filing Meeting		30		01/31/00		
Filed/Not Filed Letter Prepared & Mailed		45		02/15/00		
BIMO & GMP INSP REQUESTED						
SCIENTIFIC REVIEW						
Clinical Review #1		105	01/31/00	05/15/00		
Clinical Review #2		105	01/31/00	05/15/00		
Engineering/Physics Review		105	01/31/00	05/15/00		
Chemistry/Biomaterial Review		105	01/31/00	05/15/00		
Biological/Sterility Review		105	01/31/00	05/15/00		
Toxicology/Biocompatibility Review		105	01/31/00	05/15/00		
Statistics Review		105	01/31/00	05/15/00		
Labelling Review		105	01/31/00	05/15/00		
Other Review		105	01/31/00	05/15/00		
Reviewer's Recomm/Proposed SSED Due		10	05/15/00	05/25/00		
Branch Chief's Review		7	05/25/00	06/01/00		
Associate Director's Review		7	06/01/00	06/08/00		
Division Director's Review		7	06/08/00	06/15/00		
(Decision) Ltr/Pkg to POS		7	06/15/00	06/22/00		
POS Logout				06/29/00		

Prepared: 04/24/96

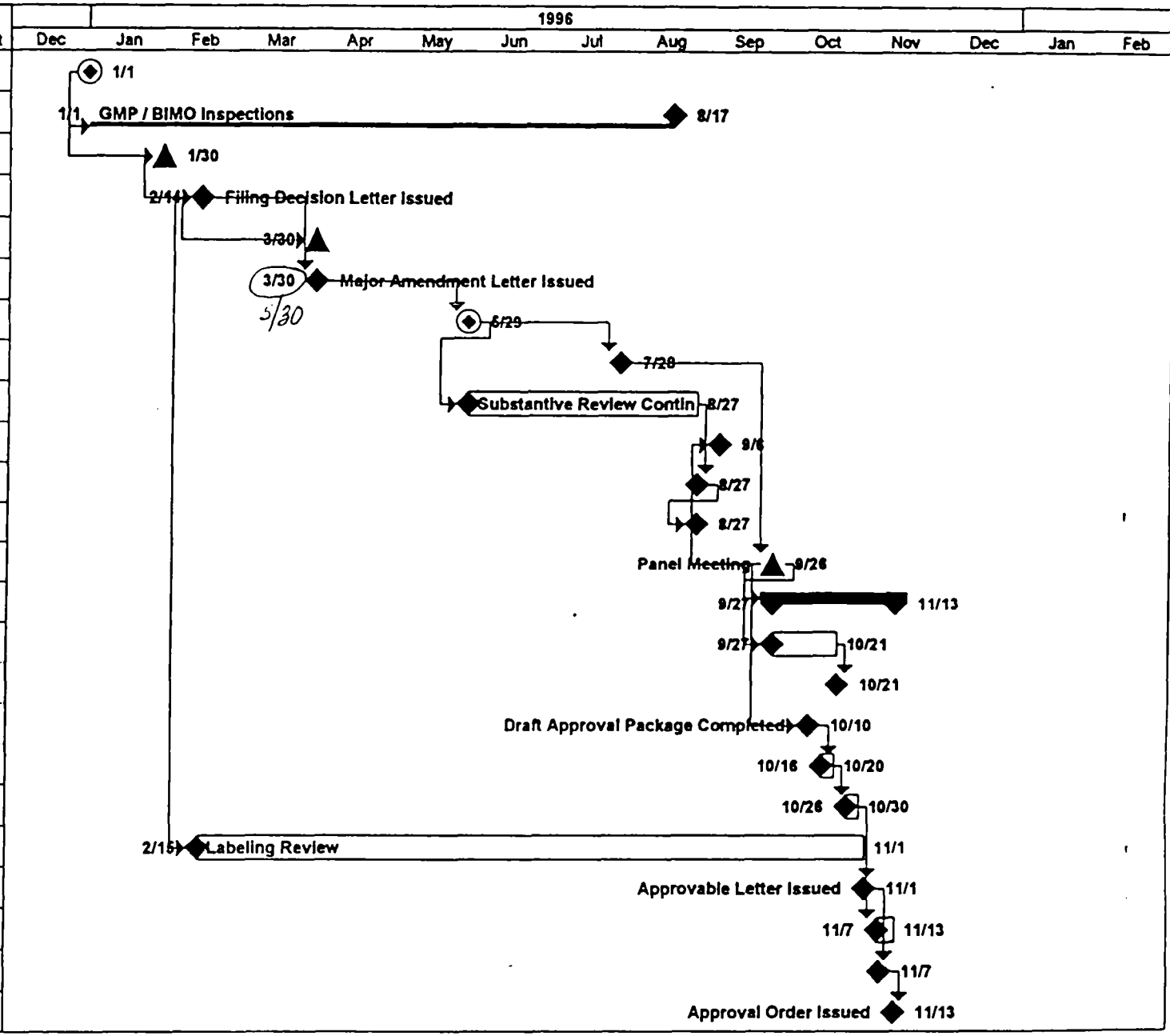
PILOT

PMA Number

Master Gantt Chart for PMAs

Lead Reviewer

ID	Task Name	Durat
1	PMA 9600XX Reciept Date	0d
2	GMP / BIMO Inspections	230d
3	30 Day Fileability Decision & Plan Meet	0d
4	45 Day - Filing Decision Letter Sent	0d
5	90 Day Status Meeting	0d
6	MAJOR AMENDMENT LETTER ISSUED	0d
7	MAJR AMEND RESPONSE RECEIVED	0d
8	Panel Meeting Scheduled	0d
9	Substantive Review Continues	90d
10	Panel Package Sent	0d
11	Prepanel SSED Completed	0d
12	Prepanel Briefing of Director, ODE	0d
13	Panel Meeting	0d
14	POSTPANEL PHASE	48d
15	Panel Requirements Addressed	25d
16	Press Release Finalized	0d
17	Draft Approval Package Completed	0d
18	PMA Division Review Sign-Off	5d
19	POS Review & Comment on Approval Pkg	5d
20	Labeling Review (Team & Panel)	261d
21	Approvable Letter Issued	0d
22	PMA Approval Package to Director, ODE	7d
23	Approvable Response Received	0d
24	APPROVAL ORDER ISSUED	0d



Date Printed

Task

Milestone

Summary

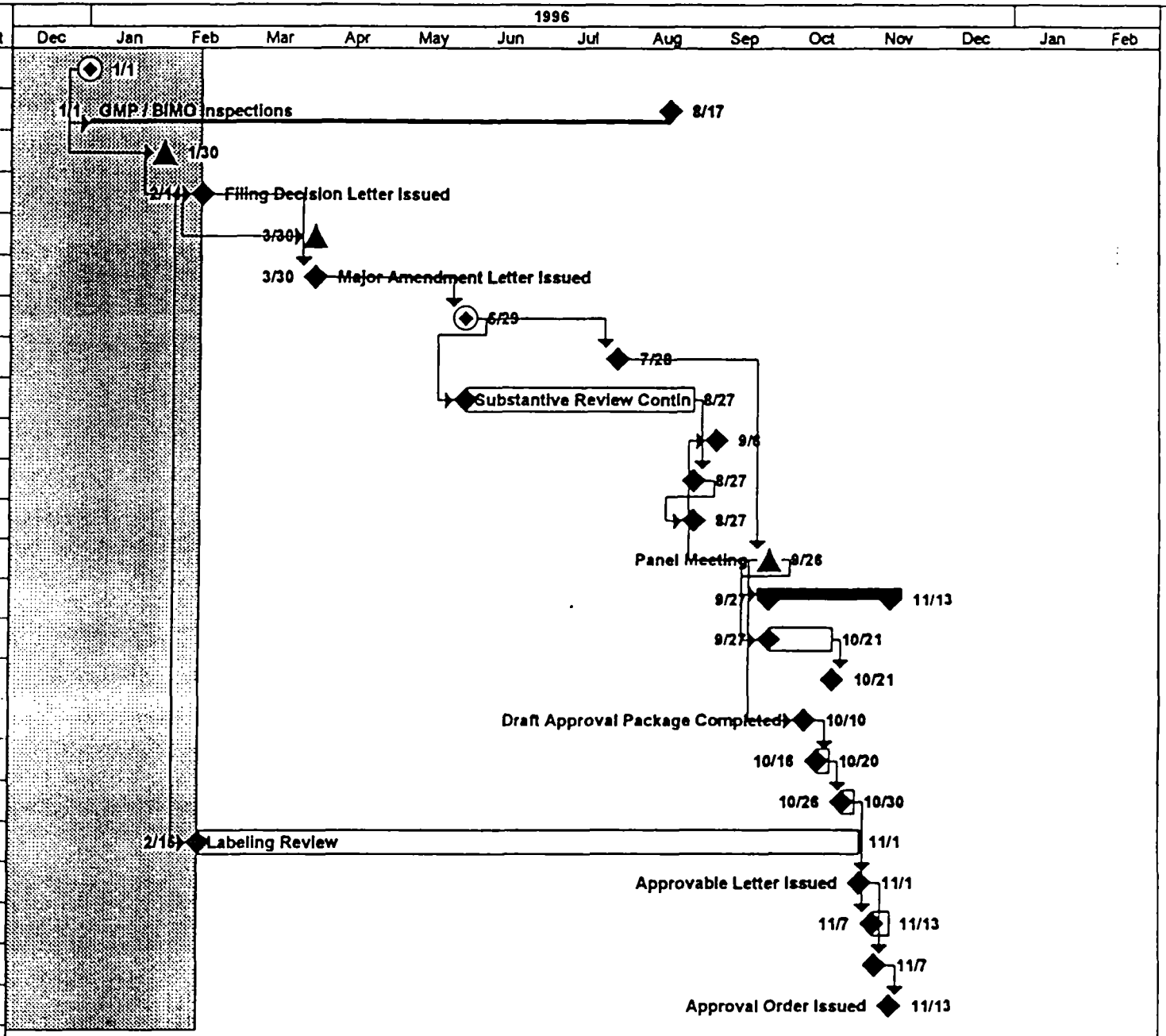
PILOT

PMA Number

Master Gantt Chart for PMAs

Lead Reviewer

ID	Task Name	Durat
1	PMA 9600XX Reciept Date	0d
2	GMP / BIMO Inspections	230d
3	30 Day Fileability Decision & Plan Meet	0d
4	45 Day - Filing Decision Letter Sent	0d
5	90 Day Status Meeting	0d
6	MAJOR AMENDMENT LETTER ISSUED	0d
7	MAJR AMEND RESPONSE RECEIVED	0d
8	Panel Meeting Scheduled	0d
9	Substantive Review Continues	90d
10	Panel Package Sent	0d
11	Prepanel SSED Completed	0d
12	Prepanel Briefing of Director, ODE	0d
13	Panel Meeting	0d
14	POSTPANEL PHASE	48d
15	Panel Requirements Addressed	25d
16	Press Release Finalized	0d
17	Draft Approval Package Completed	0d
18	PMA Division Review Sign-Off	5d
19	POS Review & Comment on Approval Pkg	5d
20	Labeling Review (Team & Panel)	261d
21	Approvable Letter Issued	0d
22	PMA Approval Package to Director, ODE	7d
23	Approvable Response Received	0d
24	APPROVAL ORDER ISSUED	0d



Date Printed

Task

Milestone

Summary

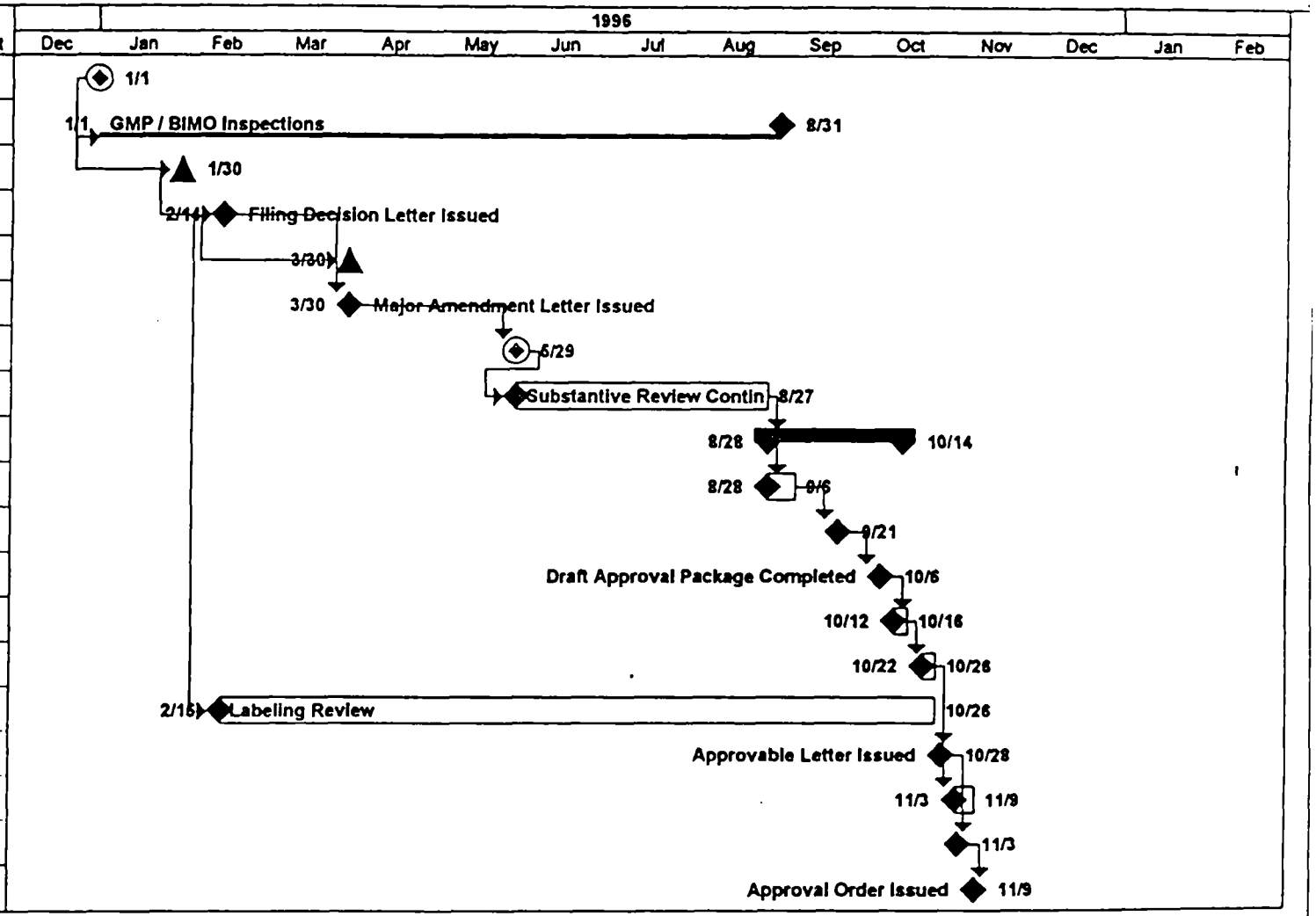
PILOT

PMA Number

Master Gantt Chart for PMAs

Lead Reviewer

ID	Task Name	Durat
1	PMA 9600XX Reciept Date	0d
2	GMP / BIMO Inspections	244d
3	30 Day Fileability Decision & Plan Meet	0d
4	45 Day - Filing Decision Letter Sent	0d
5	90 Day Status Meeting	0d
6	MAJOR AMENDMENT LETTER ISSUED	0d
7	MAJR AMEND RESPONSE RECEIVED	0d
8	Substantive Review Continues	90d
9	PMA CLOSURE PHASE	48d
10	Review Wrap-up	10d
11	SSED Completed	0d
12	Draft Approval Package Completed	0d
13	PMA Division Review Sign-Off	5d
14	POS Review & Comment on Approval Pkg	5d
15	Labeling Review (Team)	255d
16	Approvable Letter Issued	0d
17	PMA Approval Package to Director, ODE	7d
18	Approvable Response Received	0d
19	APPROVAL ORDER ISSUED	0d



Date Printed | Task | Milestone | Summary

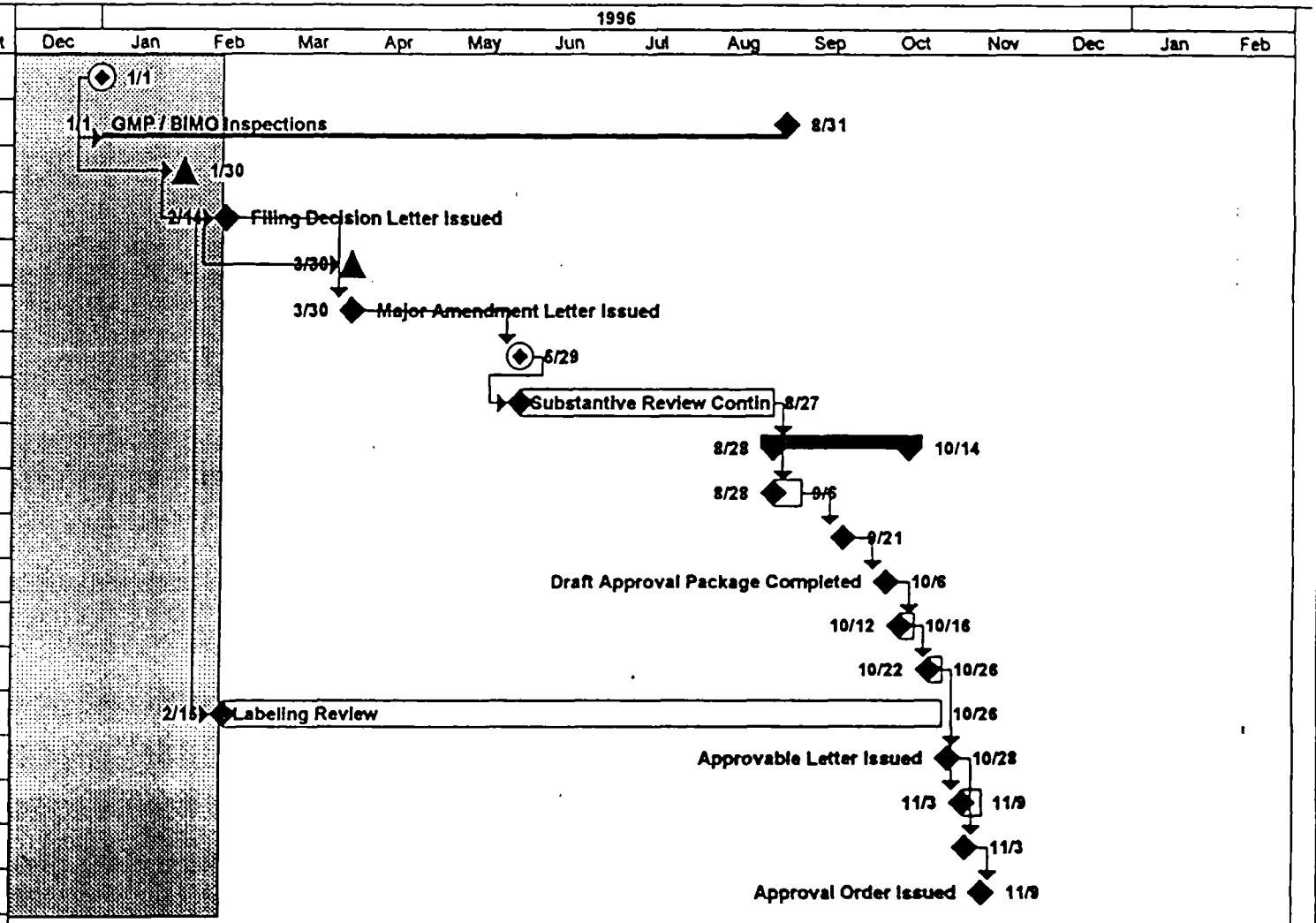
PILOT

PMA Number

Master Gantt Chart for PMAs

Lead Reviewer

ID	Task Name	Durat
1	PMA 9600XX Reciept Date	0d
2	GMP / BIMO Inspections	244d
3	30 Day Fileability Decision & Plan Meet	0d
4	45 Day - Filing Decision Letter Sent	0d
5	90 Day Status Meeting	0d
6	MAJOR AMENDMENT LETTER ISSUED	0d
7	MAJR AMEND RESPONSE RECEIVED	0d
8	Substantive Review Continues	90d
9	PMA CLOSURE PHASE	48d
10	Review Wrap-up	10d
11	SSED Completed	0d
12	Draft Approval Package Completed	0d
13	PMA Division Review Sign-Off	5d
14	POS Review & Comment on Approval Pkg	5d
15	Labeling Review (Team)	255d
16	Approvable Letter Issued	0d
17	PMA Approval Package to Director, ODE	7d
18	Approvable Response Received	0d
19	APPROVAL ORDER ISSUED	0d



Date Printed | Task | Milestone | Summary

Clinton Presidential Records
Digital Records Marker

This is not a presidential record. This is used as an administrative marker by the William J. Clinton Presidential Library Staff.

This marker identifies the place of a tabbed divider. Given our digitization capabilities, we are sometimes unable to adequately scan such dividers. The title from the original document is indicated below.

J

Divider Title: _____

FACT SHEET--GROUP PRODUCTIVITY INCENTIVE PROGRAM

1. *DESCRIPTION*--In the beginning of the fiscal year, CDRH will set aside operating funds (if available) to transfer up to $15,000 to center organizations or cross-cutting teams selected for superior group productivity. The focus here is on recognizing group productivity rather than individual performance. In contrast to cash awards, which go directly to the individual(s) involved; money for this incentive program will be transferred as operating dollars to the organizations or project teams. The funds will be used at the group's discretion for purposes that operating funds are regularly used: like training, travel and equipment. Funds for cross-cutting teams will go to the organization of the team leader, who will be responsible for assuring that they are spent for the benefit of team members.

2. *ELIGIBILITY*--This productivity incentive program is open to any CDRH organization (e.g. division or branch), group or project team. Nominees may include project teams with employees from several different organizations, including employees in other parts of FDA or other Federal agencies. This incentive program is intended to supplement, not replace, existing individual and group cash and honor awards.

3. *FORMAT*--The nomination should be no more than one page--No attachments

- Name of organization/project team being nominated;
- Description of superior group productivity (briefly outlining what was done, when it was done, why the productivity was superior, and what important result or outcome the productivity achieved);
- Number of employees involved (if project team, list employees and Offices); and
- Signature of nominator.

4. *NOMINATION PROCESS*--Nominations for these awards can be made by CDRH Deputy or Office Directors any time during the fiscal year. OSM will remind Office Directors to submit nominations two weeks in advance of future Awards Committee meetings. Nominations should be forwarded to the CDRH Incentive Awards Officer in OSM, who will coordinate their review by the CDRH Awards Committee. Selections will be made throughout the year by the Office of the Center Director, based on recommendations by the CDRH Awards Committee.

5. *PRESENTATION*--Selections will be made throughout the year, but since operating funds are more useful early in the year, we will try to disburse most of the money before the last few months of the fiscal year.