Overview of FDA Modernization Act of 1997, Medical Device Provisions

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Foreword

The Center for Devices and Radiological Health (CDRH) develops and implements national programs to protect the public health in the fields of medical devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical devices; to promote quality in mammographic services; and to control unnecessary human exposure to potentially hazardous radiation, and to ensure the safe, efficacious use of such radiation.

The basic framework governing the regulation of medical devices is established in the Medical Device Amendments to the Federal Food, Drug, and Cosmetic (FFD&C) Act. The Medical Device Amendments were enacted on May 28, 1976. The FFD&C Act was again amended with respect to the regulation of medical devices by the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992. New provisions governing the export of FDA regulated products, including medical devices, were established in the FDA Export Reform and Enhancement Act of 1996.

The FFD&C Act was most recently amended by the Food and Drug Administration Modernization Act of 1997 (the Modernization Act). Signed into law on November 21, 1997, the Modernization Act contained provisions related to all products under FDA's jurisdiction. This document summarizes each device-related section of the Modernization Act in "plain English." It is not intended to be interpretive or to set forth Agency policy for implementation.

We welcome your comments and requests for further information.

D. Bruce Burlington, M.D.
Director
Center for Devices and Radiological Health

Preface

The Medical Device Amendments of 1976 mandated the establishment of "an identifiable office to provide technical and other nonfinancial assistance to small manufacturers of medical devices to assist them in complying with the requirements of the FFD&C Act." The Division of Industry and Consumer Education(DICE) in the Office of Communication, Education, and Radiation Programs was established to meet this requirement. DICE develops educational materials and sponsors workshops and conferences to provide firms with firsthand working knowledge of medical device requirements and compliance policies.

This booklet covers the medical device provisions of the Modernization Act, which amends the FFD&C Act.

For further information, contact the appropriate office within CDRH or call DICE at 1-800-638-2041 or 301-796-7100, or Email us at **dice@fda.hhs.gov (mailto:dice@fda.hhs.gov)**.

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number 1174 to identify the guidance you are requesting.

Comments on this booklet, related workshops, and other DICE activities are always welcome.

John Stigi
Director
Division of Industry and Consumer Education

Introduction

Congress amended the FFD&C Act in an effort to streamline the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market.

With respect to medical devices, the FDA is directed to focus its resources on the regulation of those devices that pose the greatest risk to the public and those that offer the most significant benefits. The FDA must base its decisions on clearly defined criteria and provide for appropriate interaction with the regulated industry. The new legislation assumes that enhanced collaboration between the FDA and regulated industry will accelerate the introduction of safe and effective devices to the U.S.

The Modernization Act was signed into law by President Clinton on November 21, 1997. Most provisions went into effect on February 19, 1998 (90 days from enactment of the Modernization Act), while some have different effective dates or require implementing regulations.

This document presents a summary of each device related section of the Modernization Act, combined under relevant headings, i.e. IDE's, PMA's, 510(k)'s. It includes a brief description of the new provisions, including effective dates, and identifies applicable Federal Register (FR) documents.

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Sections Related to: Investigational Device Exemptions

- **Section 201 - Changes to Protocols and Devices**
- **Section 201 - Early Collaboration of Data Requirements for Clinical Studies**
- **Section 205 - Meeting on Evidence of Effectiveness for PMA's**
- **Section 203 - Expanded Humanitarian Device Exemption (HDE)**
- **Section 402 - Expanded Access to Investigational Devices**
- **Section 214 - Practice of Medicine**

Section 201 - Changes to Protocols and Devices

- Clinical Protocol
  Allows changes to be made to the clinical protocol, without additional FDA approval, that do not affect:
  1) validity of the data resulting from the study;
  2) the risk to benefit ratio relied upon to approve the protocol;
  3) the scientific soundness of the study, or
  4) the rights, safety or welfare of the human subjects.
- Device Manufacture and Design
  Allows developmental changes to be made to the device in response to information gathered in the trial (including manufacturing changes), without additional FDA approval, provided they do not significantly affect the design or basic principles of operation of the device.
- Sponsor Requirements
  The sponsor or applicant is responsible for determining that the change in the protocol or the modification of the device satisfies the conditions described above and must make that determination on the basis of credible information.
  The sponsor of the investigation must notify FDA within 5 days after making such a change.
  Effective: Upon promulgation of a regulation due by November 21, 1998.

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Section 201 - Early Collaboration of Data Requirements for Clinical Studies

Sponsors that intend to perform a clinical study of any Class III device or any implantable device in any class, will be given an opportunity to meet with FDA to discuss their investigational plan, including the clinical protocol, for the purpose of reaching an agreement on the investigational plan before they apply for an investigational device exemption (IDE).
A written request for this meeting from the sponsor to FDA is required. The request shall include a detailed description of the device, proposed conditions of use and a proposed investigational plan (including clinical protocol), and, if available, expected performance of the device. The FDA has 30 days to meet with the sponsor after receipt of the written request.
An official record will be made of any agreement that is reached between the sponsor and the FDA. This agreement will be binding and is not subject to change except:

1) with written agreement of the sponsor; or
2) if FDA decides that a substantial scientific issue essential to determining the safety or effectiveness of the device has been identified following the initial agreement. In this case, the decision by FDA must be in writing and follow an opportunity for the sponsor to meet with the Agency to discuss the issue identified.

Effective: February 19, 1998.

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Section 205 - Meeting on Evidence of Effectiveness for PMA's

Sponsors planning to submit a Premarket Approval Application (PMA) can submit a written request to FDA for a meeting to determine the type of information (valid scientific evidence) that is necessary to support the effectiveness of their device.
The request must include a detailed description of the device, proposed conditions of use, an investigational plan and, if available, information regarding the device's expected performance. The FDA must meet with the requester and communicate the Agency's determination of the type of data that will be necessary to demonstrate effectiveness in writing within 30 days after the meeting.
When making this determination, FDA must determine that the information specified is necessary to provide a reasonable assurance that the device is effective and must have considered the least burdensome method of evaluation that is likely to result in approval.
FDA's determination will be binding and not subject to change unless the Agency determines that the decision could be contrary to the public health.
While the meeting under Section 205 is intended to focus on the type of valid scientific evidence that will be necessary and the meeting under Section 201 is intended to focus on the actual protocol, FDA believes the purposes of the meetings can usually most effectively be accomplished in a single meeting. However, some sponsors may request and benefit from two separate meetings.
Effective: February 19, 1998

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Section 203 - Expanded Humanitarian Device Exemption (HDE)

- Approval of Applications
  Requires FDA approval or denial of an HDE within 75 days (rather than 180 days) following the receipt of the application. HDEs are no longer limited to renewable terms of 18 months. The term of the HDE is now indefinite, but FDA may require a sponsor to demonstrate continued compliance any time:

  1) the Agency believes it is necessary to protect public health; or
  2) the Agency has reason to believe the criteria for an HDE is not being met.

  Approval of an HDE may not be withdrawn unless the sponsor is given an opportunity for an informal hearing.

- Emergency Use
  Emergency use by a physician of a device with an approved HDE is permitted when approval by an Institutional Review Board (IRB) cannot be obtained in time. Following emergency use, the

physician is required to notify the IRB. The IRB will be provided with the name of the patient, the device used, and the reason for the use.

- Timeframes
  The 5 year "sunset" provision limiting the use of HDEs has been removed.
  Effective: February 19, 1998

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*** Section 402 - Expanded Access to Investigational Devices**

- * This provision also affects other products in addition to medical devices that are regulated by the FDA. However, any processes or procedures that CDRH establishes will apply only to medical devices.
- Emergency Use
  The FDA can permit the shipment of an investigational device for the purpose of diagnosing, monitoring or treating a serious disease or condition in an emergency situation.
- Individual Patient Access to Investigational Devices
  Allows any person, acting through a physician, to request from a manufacturer or a distributor, an investigational device subject to the provisions of Section 520(g) of the FFD&C Act to diagnose, treat or monitor a serious disease or condition, and allows the manufacturer or distributor to supply the device if the following criteria are met:

  1) the licensed physician determines that there is no comparable or satisfactory alternative treatment and that the risk from use of the device does not exceed the risk of the disease or condition;
  2) the FDA determines there is sufficient evidence of safety and effectiveness to support the use of the device;
  3) the FDA determines that providing the device will not interfere with clinical investigations to support marketing approval; and
  4) the sponsor or investigator submits a protocol to FDA describing the use of the device in a single patient or in small groups of patients.

- Treatment Investigational Device Exemption
  Following the submission of a protocol by a physician or sponsor intended to provide widespread access to an investigational device, the FDA shall permit treatment use of the device for patients outside the clinical investigation to support marketing approval, if the Agency determines:

  1) the use of the device is intended for the diagnosis, monitoring or treatment of a serious or immediately life-threatening disease or condition;
  2) there is no comparable or satisfactory alternative;

3) the device is being clinically evaluated under an approved investigational device exemption or all clinical investigations to support marketing approval have been completed;
4) the sponsor is actively pursuing marketing approval;
5) the treatment use will not interfere with the enrollment of patients in ongoing clinical investigations;
6) for serious diseases there is sufficient evidence of safety and effectiveness to support treatment use; and
7) for immediately life-threatening diseases the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the device may be effective in treatment use and would not put patients at an unreasonable risk.

The FDA may inform national, state and local medical associations and other appropriate persons of the availability of the investigational device for treatment use.

The FDA may terminate expanded access under this section if the conditions under this section are no longer being met.
Effective: February 19, 1998

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Section 214 - Practice of Medicine

Nothing in this Act limits or interferes with the authority of a physician to prescribe or administer any legally marketed device to treat any disease or condition if done within a legitimate health care practitioner-patient relationship. However, FDA retains its current authority to restrict the sale, distribution, or labeling of devices and to prohibit the promotion of unapproved uses.
Effective: February 19, 1998

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Sections Related to Premarket Approval

- **Section 201 - Data from Previous Investigations**
- **Section 202 - Special Review for Certain Devices**
- **Section 205 - Scope of Review/Collaborative Determinations of Device Data Requirements**
- **Section 207 - Risk Based Classification of Postamendment Class III Devices**
- **Section 208 - Classification Panels**

- **Section 209 - For PMA Collaborative Review Process**
- **Section 216 - Use of Data**
- **Section 216 - Product Development Protocol (PDP)**
- **Section 217 - Clarification of the Number of Required Clinical Investigations for Approval**
- **Section 403 - Approval of Supplemental Applications**

Section 201 - Data from Previous Investigations

Allows for the submission of data from investigations of earlier versions of a device in support of safety and effectiveness. Such data is only valid if modifications to earlier versions of the investigational device, whether made during or after the investigation, do not constitute a significant change that would invalidate the relevance of the data. In addition, this section allows for the submission of data or information relating to an approved device that are relevant to the design and intended use of a device for which an application is pending, provided the data are available for use under the FFD&C Act. (i.e. available by right of reference or in the public domain)
Effective: February 19, 1998

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Section 202 - Special Review for Certain Devices

The FDA will provide special review, which can include expedited processing of a Premarket Approval (PMA) application, for certain devices intended to treat or diagnose life threatening or irreversibly debilitating diseases or conditions. To receive special review, the devices must meet one of the following criteria:
1) the device represents a breakthrough technology;
2) there are no approved alternatives;
3) the use of the device offers significant advantages over existing approved alternatives; or
4) availability is in the best interest of the patients.

Effective: February 19, 1998

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Section 205 - Scope of Review/Collaborative Determinations of Device Data Requirements

- Labeling Claims for PMA's
  The FDA is to rely on the conditions of use submitted as proposed labeling in the PMA application, so long as the proposed labeling is neither false nor misleading. In determining

whether or not such labeling is false or misleading, FDA shall fairly evaluate all material facts pertinent to the proposed labeling. This provision is consistent with the way FDA has always reviewed PMAs.
Effective: February 19, 1998

- Notices/PMA Supplements for Manufacturing Changes
  PMA supplements are required for all changes that affect safety or effectiveness, unless such change involves modifications in a manufacturing procedure or method of manufacturing. Manufacturing changes affecting safety or effectiveness may require only a written notice to FDA, which describes the changes in detail and which summarize the information that supports the change. The written notice must also state that the changes were made in accordance with the Quality Systems Regulation (GMPs). The devices subject to manufacturing changes can be distributed 30 days after a notification report is submitted to FDA unless the Agency notifies the submitter that the notice is not adequate.
  If FDA deems the notice to be inadequate, FDA may request further information or require a PMA supplement. The FDA shall review the supplement within 135 days of receipt. The initial 30 day notification review period will be deducted from the 135 day supplement review period if the original notification meets the appropriate content requirements for a PMA supplement.
  This notification procedure applies only to supplements relating to changes in manufacturing procedures or methods.
  Effective: February 19, 1998
- PMA Supplements for Design Changes
  PMA supplements for incremental changes in design affecting safety and effectiveness can be approved based on:

  1) non-clinical data that demonstrate the change creates the intended additional capacity, function, or performance of the device; and
  2) clinical data included in the original PMA application or any supplement to that application that provides reasonable assurance of safety and effectiveness.

  However, if needed, FDA may require a sponsor to submit new clinical data to demonstrate safety and effectiveness.
  Effective: February 19, 1998
- Postmarket Controls to Reduce Data Requirements
  While making a determination regarding the approval of a PMA application, FDA must consider if postmarket controls can be relied on to reduce the extent of data pertaining to effectiveness that otherwise would be required to support approval.
  Effective: February 19, 1998

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Section 207 - Risk Based Classification of Postamendment Class III Devices

An applicant who submits a Premarket Notification Submission [510(k)] and receives a Not Substantially Equivalent (NSE) determination, placing the device into a Class III category, can request FDA to classify the product into Class I or II.
The request must be in writing and sent within 30 days from the receipt of the NSE determination. In addition, the request must include a description of the device, reasons for the recommended classification (into Class I or II), and information to support the recommendation. Within 60 days from the date the written request is submitted to FDA, the Agency must classify the device by written order.
If FDA classifies the device into Class I or II, this device can be used as a predicate device for other 510(k)s.
However, if FDA determines that the device will remain in Class III, the device cannot be distributed until the applicant has obtained an approved Premarket Approval (PMA) application or an approved Investigational Device Exemption (IDE).
Within 30 days of notifying the applicant of the determination that the device has been classified into Class I or Class II, FDA will announce the final classification in the Federal Register.
Effective: February 19, 1998

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Section 208 - Classification Panels

- Scheduling of Meetings
  Meetings shall be scheduled so that the FDA timeframes for approval of PMA and 510(k) applications can be met.
- Review by the Panel
  PMA applicants shall have:

  1) the same access as FDA to data and information submitted by FDA to a classification panel, except data not available for public disclosure;
  2) the opportunity to submit information based on the PMA, through FDA, to the panel; and
  3) the same opportunity as FDA to participate in panel meetings.
- Final Decision
  If the final decision to approve or disapprove an application differs from the panel recommendation, reasons for this determination shall be provided to the applicant in writing by FDA.
  Effective: February 19, 1998

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Section 209 - For PMA Collaborative Review Process

The FDA must, upon the written request of the applicant, meet with that party within 100 days of receipt of the filed PMA application to discuss the review status of the application. With the concurrence of the applicant, a different schedule may be established.
Prior to this meeting, FDA must inform the applicant in writing of any identified deficiencies and what information is required to correct those deficiencies. The FDA must also promptly notify the applicant if FDA identifies additional deficiencies or of any additional information required to complete Agency review.
Effective: February 19, 1998

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Section 216 - Use of Data

- The FDA can now use certain information, contained in approved PMA applications, six years after the application has been approved to:

    1) approve another PMA application;
    2) determine whether a Product Development Protocol (PDP) has been completed;
    3) establish a performance standard or a special control; or
    4) classify or reclassify another device.

- Information available for the Agency to use would include clinical and non-clinical tests or studies in the application that were used to demonstrate safety and effectiveness. However, it would exclude trade secret information such as manufacturing methods or device composition.
  Effective: February 19, 1998

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Section 216 - Product Development Protocol (PDP)

The FDA is no longer required to refer all PDP's to panel. The Agency now has discretion to refer a proposed protocol to an advisory panel for recommendation regarding approval before making a determination. However, FDA is required to refer the proposed protocol to the panel if requested by the submitter, unless the protocol and accompanying data substantially duplicate information that has been reviewed by the panel previously.
Effective: February 19, 1998

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Section 217 - Clarification of the Number of Required Clinical Investigations for Approval

The FDA can rely on one or more clinical investigations to conclude that a device that is the subject of a PMA application is effective or to establish a device performance standard.
Effective: February 19, 1998

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Section 403 - Approval of Supplemental Applications

- Standards for Prompt Review
  The FDA will publish, in the Federal Register (FR), standards the Agency will use to assure prompt review of a PMA supplement.
  Effective: FR notification due by May 20, 1998
- Guidance to Industry
  The FDA will publish final guidance to clarify the requirements for, and facilitate the submission of, data to support a PMA supplement. This guidance will:

  1) clarify when published information can be used as the basis of approval;
  2) specify data requirements that will avoid duplication of previously submitted data used to support the original PMA application; and
  3) identify types of supplements that are eligible for priority review.

  Effective: Guidance due by May 20, 1998
- Designated Individual
  A person will be designated from the Center for Devices and Radiological Health to encourage prompt review of supplements by FDA and to work with sponsors to facilitate both the development and submission of data necessary to support a PMA supplement.
  Effective: February 19, 1998
- Collaboration with Outside Organizations
  The FDA will implement programs and policies to foster collaboration with outside organizations, including the National Institutes of Health, medical and scientific associations, and others for purposes of identifying studies that may support PMA supplements and to encourage sponsors to make supplemental applications or conduct further research to support supplements.
  Effective: February 19, 1998

Sections Related to Premarket Notification [510(k)]

- **Section 205 - Collaborative Determinations of Device Data Requirements**
- **Section 206 - Premarket Notification**
- **Section 209 - Certainty of Review Timeframes**

- **Section 210 - Accreditation of Persons for Review of Premarket Notification Reports**

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Section 205 - Collaborative Determinations of Device Data Requirements

- Postmarket Controls to Reduce Data Requirements
  While making a determination regarding the clearance of a [510(k)] application, FDA must consider if postmarket controls can be relied on to expedite such clearance.
  Effective: February 19, 1998
- Additional Information
  When FDA requests additional information to demonstrate equivalence for devices that have different technological characteristics than the predicate, FDA shall only request information necessary to make a determination of substantial equivalence and shall consider the least burdensome means of demonstrating substantial equivalence.
  Effective: February 19, 1998
- Labeling Claims for 510(k)'s
  This section requires that a determination about the intended use of a device be based on the proposed labeling submitted in the 510(k) application. In making the determination, however, the Director of the Office of Device Evaluation (ODE) may determine that there is a reasonable likelihood that the device will be used for an intended use not identified in the labeling that could cause harm. In such cases, the Director shall communicate FDA's concerns to the 510(k) applicant in writing within 10 days of making the determination and require a statement in the labeling specifying limitations on uses of the device.
  The device will be found substantially equivalent if it otherwise meets the requirements for substantial equivalence and if its labeling conforms to the limitations specified by FDA. Responsibility for making such labeling determinations cannot be delegated below the Director of the Office of Device Evaluation (ODE).
  Effective: February 19, 1998
  Sunset clauses: Expires November 21, 2002

Section 206 - Premarket Notification

Exemption from 510(k)
A 510(k) submission is not required for a Class I device unless the Class I device:

1) is intended for a use which is of substantial importance in preventing impairment of human health; or
2) presents a potential unreasonable risk of illness or injury.

A 510(k) submission will not be required for specified Class II devices. The FDA plans to publish in the Federal Register, within 60 days of enactment of the Modernization Act, a list of

Class II devices that are exempt from 510(k).
After the list of Class II exempt devices has been published, additional Class II devices may be exempted on FDA's own initiative or by petition of an interested person. The FDA will publish in the Federal Register a notice of intent to exempt these device types and provide a 30 day period for comment. Within 120 days after the issuance of the notice, FDA will publish a final order regarding the exemption of the subject devices. If FDA fails to respond to a petition within 180 days, it will be deemed granted.
Effective: January 20, 1998 upon publication of 510(k) exempt Class II devices.

- Substantial Equivalence
  The FDA cannot withhold a 510(k) decision for failure of a firm to comply with any provision of the FFD&C Act unrelated to a substantial equivalence decision, including failure by the firm manufacturing the device to comply with GMPs, unless, FDA finds that failure to comply with such regulations will potentially present a serious risk to human health.

  Effective: February 19, 1998
- General/Specific Uses

  The FDA will publish guidance within 270 days of enactment specifying general principles it will follow for determining when a specific intended use is not reasonably included within a general use for the purpose of determining substantial equivalence.

  Effective: Guidance due by August18, 1998.

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Section 209 - Certainty of Review Timeframes

The law directs FDA to review premarket notifications and make a determination not later than 90 days after receiving the report.
Effective: February 19, 1998

Section 210 - Accreditation of Persons for Review of Premarket Notification Reports

Background

The FDA is authorized to expand the scope of the existing Third Party 510(k) review program. The FDA must accredit persons to conduct initial 510(k) reviews no later than one year after enactment. Accredited persons may not review:

1) Class III devices;
2) Class II devices that are permanent implants or life sustaining or life supporting; or
3) Class II devices which require clinical data, except the number in this group must not be

more than 6% of total submissions (as defined by statute).

- Following review by an accredited party, FDA must act within 30 days of receipt of the accredited party's recommendation to accept the recommendation or change the classification of the device. If FDA changes the recommendation, it will notify the applicant and the third party explaining in detail the reasons for the change.

Accreditation

By May 20, 1998, FDA will publish in the Federal Register criteria it will use to accept or deny accreditation to persons who submit requests to perform reviews. The FDA must respond to a request for accreditation within 60 days of receipt.

The FDA may suspend or withdraw accreditation after providing notice and opportunity for an informal hearing when the accredited body:

1) is substantially not in compliance with this section;
2) poses a threat to public health; or
3) fails to act in a manner consistent with the purposes of this section.

The FDA must make periodic onsite visits to accredited persons to audit performance and has access to and authority to copy and verify records. Minimum qualifications of accredited persons include:

1) shall not be a Federal Government employee;
2) must be an independent organization not owned or controlled by a manufacturer, supplier or vendor of devices and have no organizational, material, or financial affiliation with such a manufacturer, supplier or vendor;
3) must be a legally constituted entity permitted to act as a third party;
4) shall not engage in design, manufacture, promotion or sale of devices;
5) operate in accordance with generally accepted professional and ethical business practices and agree in writing that at a minimum it will:

(i) certify that reported information accurately reflects data reviewed;
(ii) limit work to that for which competence and capacity are available;
(iii) treat information received, records, reports, and recommendations as proprietary information;
(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and
(v) protect against the use of officers or employees to conduct reviews when that person has a financial conflict of interest regarding the device, and annually disclose in a public report the extent to which officers and employees have maintained compliance with requirements relating to financial conflicts of interest.

Effective: May 20, 1998 (publish criteria to accredit persons)

Records Required of Third Parties

Accredited parties must maintain records:

1) documenting the training qualifications of all employees associated with conducting reviews;
2) documenting the procedures used by the employees for handling confidential information; and
3) documenting the compensation arrangements and procedures used to identify and avoid conflicts of interest.

These records are available upon request to FDA at all reasonable times and may be viewed, copied, or verified. Within 15 days of receipt of a written request from FDA, the accredited party shall make available copies of the requested records at the place designated by FDA.

It is a prohibited act for an accredited party to:

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

Access to Accredited Persons

The FDA must provide each person who wishes to use an accredited person a panel of at least two accredited bodies from which to choose. Compensation for the review will be based on agreement between the parties.

Progress Reports to Congress

Required reports include:

1) an annual FDA report to Congress that includes the names of all accredited persons, the activities they are accredited to perform, and the name of each body whose accreditation has been withdrawn.
2) an FDA report to Congress, to be published in the Federal Register no later than November 21, 2000, addressing whether the limitation on accredited body review of Class II devices requiring clinical data should be removed.
3) a Comptroller General report to Congress describing the extent to which the accreditation program has been implemented, not later than November 21, 2002.
4) a Comptroller General evaluation report to Congress describing the extent to which use of accredited bodies assisted the Agency in reviewing 510(k)'s and the extent to which such use was contrary to the purposes of the Act, not later than 6 months before the program terminates.

Authority for the program terminates:

1) 5 years after at least 2 accredited parties are available to do 60% of the 510(k) reviews; or
2) 4 years after accredited bodies have reviewed 35% of eligible 510(k)'s,

whichever occurs first.
Effective: November 21, 1998 (accredit persons to review 510(k) reports)

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Sections Related to Device Classification

Note: Sections 206 and 207 include provisions for the classification of Class II and Class III devices. Section 206 contains requirements that exempt certain Class I and II devices from Premarket Notification. Section 207 contains a requirement that allows for classification of new, low risk Class III devices. These provisions are addressed in the Premarket Notification (**Section 206**) and Premarket Approval (**Section 207**) portions of this document.
Section 416 - Product Classification (Combination Products)
Any person who submits an application or submission for a product may recommend to FDA a classification for the product or the component of FDA the applicant believes to be most appropriate to regulate the product. The request can recommend classifying the product as a drug, biological product, device, or a combination product under Section 503(g) of the FFD&C Act.
Not later than 60 days after receipt of the request, FDA must determine the classification or the component that will regulate the product, and must provide a written statement to the requester that identifies the classification or component and the reasons for the determination. The written statement cannot be changed without consent of the requester or for public health reasons based on scientific evidence. If FDA does not respond within 60 days, the requester's recommendation becomes the final FDA determination and cannot be changed without the written consent of the requester or for public health reasons based on scientific evidence.
Effective: February 19, 1998

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Sections Related to Device Labeling

- **Section 401 - Dissemination of Information on New Uses**
- **Section 421 - Labeling and Advertising Regarding Compliance with Statutory Requirements**

Section 401 - Dissemination of Information on New Uses

- Manufacturers may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in a device's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issues, group health plans, or Federal or State agencies provided the following requirements are satisfied:
- the device is a legally marketed device;
- the information is not derived from clinical research conducted by another manufacturer, unless the manufacturer disseminating the information has permission to use the information;
- sixty (60) days prior to disseminating the information, the manufacturer submits to FDA a copy of the information and any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to safety of the new use, and a summary of such information;
- the manufacturer has complied with the requirements (discussed below) relating to a supplemental application for such use; and
- information on the new use is not false or misleading, does not pose a significant risk to public health, and is in the form of:
  1) unabridged reprints or copies of peer-reviewed, scientifically sound articles published in scientific or medical journals about clinical investigations involving the device; or,
  2) reference publications that include information about clinical investigations.
- The manufacturer includes with the information to be disseminated a prominently displayed statement disclosing:

  1. that the use is not approved or cleared by FDA;
  2. if applicable, that the information is being disseminated at the expense of the manufacturer;
  3. if applicable, the names of any authors of the information who are employees or consultants to the manufacturer or have received compensation or have a financial interest in the manufacturer;
  4. the official labeling and all updates;
  5. if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information; and
  6. the identification of any person that has provided funding for the study related to the new use.

- the manufacturer includes a bibliography of other articles from scientific reference publications or journals relating to the use that is the subject of the information.
- if FDA determines that the manufacturer fails to provide data, analyses or other written matter that is objective and balanced, FDA may require the manufacturer to disseminate additional objective and scientifically sound information that pertains to the safety and effectiveness of the

use that is the subject of the information and an objective statement of FDA that bears on the safety or effectiveness of the new use.
And:

- the manufacturer has submitted a supplemental application for such use;
  Or:
- in the case of a completed study, the manufacturer submits to FDA an application containing a certification that the studies needed for a supplemental application for the new use are completed and the supplemental application will be submitted within 6 months after the initial dissemination of information on the new use;
  Or:
- in the case of a planned study, the manufacturer submits an application to FDA containing a proposed protocol and schedule for conducting the studies needed for the supplemental application for the new use and a certification that the supplemental application will be submitted not later than 36 months after the initial dissemination of information on the new use;
  Or:
- the manufacturer submits to FDA an application for an exemption from submission of a supplemental application, and such exemption is granted.
  Manufacturers have an ongoing responsibility to provide FDA with new information about the new use and if this new information indicates that the use may present a significant risk to public health, FDA may order cessation of the dissemination of information about the use.
  The FDA may also order cessation of dissemination if the manufacturer fails to comply with the requirements for dissemination, including the requirements relating to the submission of a supplemental application. The Agency can, except in limited circumstances, also require the manufacturer to take corrective action when it orders the cessation of dissemination.
  Manufacturers are required to prepare and submit to FDA lists of titles of articles and publications that have been disseminated and the categories of providers that have received the materials. In addition, manufacturers must keep records which can be used by the manufacturer or FDA to take corrective action.
  It is a prohibited act to disseminate information in violation of the requirements of this section.
  Effective: November 21, 1998 or upon issuance of a final regulation, whichever is sooner.
  Sunset: Expires September 30, 2006 or 7 years after issuance of final regulation, whichever is later.

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Section 421 - Labeling and Advertising Regarding Compliance with Statutory Requirements

Repeals the restriction in Section 301(l) of the Federal Food, Drug and Cosmetic (FFD&C) Act, which prohibits reference to FDA approval in the labeling or advertising of medical devices that have an approved PMA or IDE.
Effective: February 19, 1998

Section Related to Device Tracking

- Section 211 - Device Tracking
  The tracking requirement has been changed to eliminate automatic mandatory tracking for certain devices. The new law gives FDA discretion to order manufacturers of certain types of Class II or Class III devices to initiate a program to track their medical devices down to the patient level. The illustrative list that has been published in 21 CFR 821 will be replaced with a list of products that FDA has ordered to be tracked.
  The types of devices subject to a tracking order may include any Class II or Class III device:
  - the failure of which would be reasonably likely to have serious adverse health consequences:
  - which is intended to be implanted in the human body for more than one year; or
  - which is intended to be a life sustaining or life supporting device used outside a device user facility.
- The Modernization Act also allows patients receiving a tracked device to refuse to release, or refuse permission to release, their name, address, social security number, or other identifying information for the purpose of tracking.
  The FDA plans to contact manufacturers of devices that have previously been identified as devices subject to tracking to indicate whether they should continue to track these devices or if tracking may be discontinued. Manufacturers currently required to track devices under Section 519(e) of the FFD&C Act should not discontinue tracking prior to communication from FDA.
  Effective: February 19, 1998

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Section Related to Postmarket Surveillance

- Section 212 - Postmarket Surveillance
  Manufacturers will no longer be automatically required to conduct postmarket surveillance studies for particular devices. Rather, FDA may order such studies to be conducted for certain Class II and Class III devices. The FDA can now order postmarket surveillance for any Class II and Class III device:
  - the failure of which would be reasonably likely to have serious adverse health consequences; or

  - which is intended to be implanted in the human body for more than one year; or
  - which is intended to be a life sustaining or life supporting device used outside a device user facility.

- Manufacturers must, within 30 days of receiving an order to conduct a postmarket surveillance study from FDA, submit, for approval, a plan for the required surveillance. The FDA may order a study for up to 36 months. Any longer period has to be mutually agreed upon by the manufacturer and FDA. If no agreement on a longer time period can be reached, then a dispute resolution process is to be followed.
  After receiving the manufacturer's proposed plan, FDA has 60 days to determine if the person designated to conduct the surveillance is qualified and experienced, and if the plan will collect useful data that can reveal unforeseen adverse events or other information necessary to protect the public health.
  All postmarket surveillance studies ordered under Section 522 of the FFD&C Act should continue at this time. The FDA plans to individually contact the manufacturers currently conducting postmarket surveillance studies to confirm whether the ongoing studies should be completed.
  Effective: February 19, 1998

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Section Related to Global Harmonization

- Section 410 - Mutual Recognition Agreements and Global Harmonization
- Good Manufacturing Practices
  The FDA shall ensure that the Quality Systems Regulation (Good Manufacturing Practices) conforms to the extent practicable with all or part of internationally recognized standards defining quality systems.
  By May 20, 1998, FDA shall make public a plan that establishes a framework for achieving mutual recognition of Good Manufacturing Practices (GMP's) inspections.
- U.S. Trade Representatives
  The FDA is directed to support the Office of the U.S. Trade Representative (USTR) by:
  1) meeting with representatives of other countries to discuss methods to reduce the burden of regulation and harmonize regulatory requirements, consistent with consumer protection; and
  2) engaging in efforts to move toward acceptance of Mutual Recognition Agreements (MRA's) relating to the regulation of devices and GMP's between the European Union and the U.S.
- Meetings
  The FDA is directed to regularly participate in meetings with representatives of other foreign governments to discuss and reach an agreement on methods and approaches to harmonize

regulatory requirements.
Effective: February 19, 1998
Effective: May 20, 1998 (publication of plan for mutual recognition of GMP)

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Sections Related to Medical Device Reporting and Recall Reports

- **Section 213 - Medical Device Reporting**
- **Section 420 - Safety Report Disclaimers**

Section 213 - Medical Device Reporting

- Distributors
  Distributors of medical devices are no longer required to report device related adverse events involving death, serious injury and malfunction to the FDA and/or the device manufacturer. Instead, distributors must keep records of complaints and make the records available to FDA upon request.

  Effective: February 19, 1998
- Annual Certification Requirement
  Repeals the requirement for manufacturers, importers and distributors to submit an annual certification, Form FDA 3381, to FDA certifying whether any adverse event reports were filed during the previous year and, if so, the number filed.
  Effective: February 19, 1998
- User Facilities
  The user facility semi-annual reporting requirement has been changed to annual reporting. The annual report will now be due on January 1 of each year. User facilities may continue to use the current semi-annual user facility report form, FDA 3419, until a revised one is issued by FDA. The identity of user facilities that are submitting MDR reports is protected from disclosure except in connection with:

  1) certain actions brought to enforce device requirements under the FFD&C Act; or
  2) a communication to a manufacturer of a device that is the subject of a report to FDA of death, serious illness or injury, or other significant adverse experience. Effective: February 19, 1998
- Sentinel System for User Facilities
  The FDA is directed to promulgate a regulation and implement a program under which the FDA limits user reporting to a subset of user facilities that constitutes a representative profile of user reports for device related deaths and serious illnesses or serious injuries. The program is called

the "Sentinel System." Until such regulation is promulgated, all user facilities continue to be subject to the current requirements of the Medical Device Reporting (MDR) regulation, 21 CFR 803. No later than November 21, 1999, FDA is directed to submit a plan to Congress to limit user reporting and a progress report on its implementation.
Effective: Upon promulgation of regulation.

- Reports of Removals and Corrections
  Repeals the requirement for reporting by distributors of any removal or correction of a device undertaken to reduce a risk to health posed by the device or to remedy a violation of the FFD&C Act that may present a risk to health. The requirement will still apply to manufacturers and importers.
  Effective: February 19, 1998

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Section 420 - Safety Report Disclaimers

The submission of a safety report on a medical device shall not be interpreted as a conclusion by the person making the submission or by the FDA that the report constitutes an admission that the product malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness.
Effective: February 19, 1998

Sections Related to Establishment Registration

- **Section 213 - Exemption of Wholesale Distributors from Establishment Registration**
- **Section 417 - Registration of Foreign Establishments**

Section 213 - Exemption of Wholesale Distributors from Establishment Registration

Wholesale distributors of devices, who do not manufacture, repackage, process, or relabel a device, are no longer required to register their establishment with the FDA.
A "wholesale distributor" is defined as any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
Effective: February 19, 1998

Section 417 - Registration of Foreign Establishments

- Foreign establishments engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported, or offered for import, into the U.S. must register their establishments and provide the FDA with the name of the U.S. agent representing their

establishment. Foreign establishments must also continue to provide FDA with a list of the devices that they are exporting to the U.S. FDA is also authorized to enter into cooperative agreements with foreign countries to ensure that non-compliant products are refused entry into the U.S.
Effective: February 19, 1998

Section Related to Device Standards

Section 204 - Device Standards
This section adds a system for recognizing national and international standards in product reviews. The FDA may, through publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standards development organization.
A person may reference the recognized standard in a Declaration of Conformity, which can be used to satisfy a premarket submission requirement [PMA or 510(k)] or other requirement under the FFD&C Act to which such a standard applies. The FDA can request supportive data. The FDA may reject the declaration if information supplied does not demonstrate that the device conforms to the standard, or if the standard is inapplicable.
The FDA may withdraw such recognition of a standard, through publication of a notice in the Federal Register, if the Agency determines that the standard is no longer appropriate for meeting a requirement.
The FDA may take action against a firm if information in the Declaration of Conformity is falsified, or for failure or refusal to provide data or information requested by FDA.
Effective: February 19, 1998

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Other Sections Related to Medical Devices

- **Section 404 - Dispute Resolution**
- **Section 405 - Informal Agency Statements**
- **Section 418 - Clarification of Seizure Authority**

Section 404 - Dispute Resolution

This requires the FDA to establish, by regulation, a process under which a sponsor, applicant, or manufacturer may request a review of a significant scientific controversy, including a review by an appropriate scientific panel or advisory committee, when no other provision of the FFD&C Act or regulation provides for such a review.

The Center plans to distribute a guidance for assisting the industry in identifying the most appropriate course of action for resolving various types of complaints.
Effective: November 21, 1998

Section 405 - Informal Agency Statements

The FDA shall develop guidance documents with public participation and make these documents publicly available both in written form and, as feasible, through electronic means.
The FDA will train employees in how to develop and use guidance documents and will monitor the development and issuance of such documents.
In developing guidance documents, FDA will ensure uniform nomenclature and internal review procedures and update and publish a list of these documents in the Federal Register. Neither FDA nor the public will be bound by the guidance documents; however, FDA will ensure that its employees do not deviate from such guidance without appropriate justification and supervisory concurrence.
FDA will obtain public participation prior to implementation of guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues unless FDA determines that prior public participation is not feasible or appropriate. In such cases where prior public participation is not feasible or appropriate, or in instances where the guidance document sets forth existing policy or minor changes, FDA will solicit public comment upon implementation.
The FDA will develop an appeals mechanism to deal with complaints regarding development and use of guidance documents.
Effective: February 19, 1998
Effective: July 1, 2000 (issue regulation on policy/procedures for development, issuance and use of guidance documents)

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Section 418 - Clarification of Seizure Authority

Any person seeking release of an imported article condemned under Section 304(d)(1) of the FFD&C Act must establish that the product was intended for export at the time it entered the United States.
Effective: February 19, 1998

- Manufacturers may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in a device's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issues, group health plans, or Federal or State agencies provided the following requirements are satisfied:
- the device is a legally marketed device;

- the information is not derived from clinical research conducted by another manufacturer, unless the manufacturer disseminating the information has permission to use the information;
- sixty (60) days prior to disseminating the information, the manufacturer submits to FDA a copy of the information and any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to safety of the new use, and a summary of such information;
- the manufacturer has complied with the requirements (discussed below) relating to a supplemental application for such use; and
- information on the new use is not false or misleading, does not pose a significant risk to public health, and is in the form of:
  1) unabridged reprints or copies of peer-reviewed, scientifically sound articles published in scientific or medical journals about clinical investigations involving the device; or
  2) reference publications that include information about clinical investigations.
- The manufacturer includes with the information to be disseminated a prominently displayed statement disclosing:

  1) that the use is not approved or cleared by FDA;
  2) if applicable, that the information is being disseminated at the expense of the manufacturer;
  3) if applicable, the names of any authors of the information who are employees or consultants to the manufacturer or have received compensation or have a financial interest in the manufacturer;
  4) the official labeling and all updates;
  5) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information; and
  6) the identification of any person that has provided funding for the study related to the new use.
- the manufacturer includes a bibliography of other articles from scientific reference publications or journals relating to the use that is the subject of the information.
- if FDA determines that the manufacturer fails to provide data, analyses or other written matter that is objective and balanced, FDA may require the manufacturer to disseminate additional objective and scientifically sound information that pertains to the safety and effectiveness of the use that is the subject of the information and an objective statement of FDA that bears on the safety or effectiveness of the new use.
  And:
- the manufacturer has submitted a supplemental application for such use;
  Or:

- in the case of a completed study, the manufacturer submits to FDA an application containing a certification that the studies needed for a supplemental application for the new use are completed and the supplemental application will be submitted within 6 months after the initial dissemination of information on the new use;
  Or:
- in the case of a planned study, the manufacturer submits an application to FDA containing a proposed protocol and schedule for conducting the studies needed for the supplemental application for the new use and a certification that the supplemental application will be submitted not later than 36 months after the initial dissemination of information on the new use;
  Or:
- the manufacturer submits to FDA an application for an exemption from submission of a supplemental application, and such exemption is granted.
  Manufacturers have an ongoing responsibility to provide FDA with new information about the new use and if this new information indicates that the use may present a significant risk to public health, FDA may order cessation of the dissemination of information about the use.
  The FDA may also order cessation of dissemination if the manufacturer fails to comply with the requirements for dissemination, including the requirements relating to the submission of a supplemental application. The Agency can, except in limited circumstances, also require the manufacturer to take corrective action when it orders the cessation of dissemination.
  Manufacturers are required to prepare and submit to FDA lists of titles of articles and publications that have been disseminated and the categories of providers that have received the materials. In addition, manufacturers must keep records which can be used by the manufacturer or FDA to take corrective action.
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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)