MEDICAL DEVICE APPEALS AND COMPLAINTS

Guidance On Dispute Resolution

February 1998 (First Edition)

Center for Devices and Radiological Health

CDRH

FDA

Acknowledgments

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Foreword

Medical science, particularly regulatory science, rarely involves absolutes or issues that are distinctively black or white. Often, opinions are formed and decisions are made on the basis of "best judgments." As regulators, our best judgments are to be formed in the context of the law, implementing regulations, and previous decisions on similar cases. Each new case raises unique issues and the decision "rules" offered in law or regulation are seldom so sharply drawn as to lead to only one possible conclusion.

Often there are important factual, public health or precedential factors that must be weighed in making a decision. And so, strongly held differences in viewpoints occasionally arise. When they do, we as regulators strive to achieve consistency among similar cases and emphasize the role of good science. In reviewing initial decisions, the rule-based mechanisms upon which we rely focus on facts that were relevant at the time of an original decision or action and not on new data or new arguments.

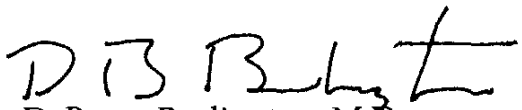
Regulating medical devices and complying with Federal regulatory requirements can be a complex job that sometimes results in conflict. I believe that people throughout the management chain in the Center for Devices and Radiological Health have done their utmost to be sure appeals and complaints have received the fair-minded and timely attention they deserve. That is not to say, of course, that we have handled every grievance perfectly or that our system cannot be improved. It can, and I am committed to doing just that.

In the coming months, I intend to appoint a Center-wide ombudsman to help resolve difficult regulatory and scientific disputes. In addition to helping mediate disputes and providing advice to industry on appropriate dispute resolution processes, the CDRH ombudsman will play a role in the implementation of section 404 of the Food and Drug Administration Modernization Act of 1997 which speaks to the resolution of scientific controversies that arise between the Agency and medical device sponsors, applicants and manufacturers.

In the meantime, and after hearing from CEOs, regulatory affairs officials and others throughout the medical device industry about the need for greater clarity with respect to available FDA dispute resolution mechanisms, we have developed this handbook to help all parties -- chiefly regulated entities -- with these situations. Starting with the basics of what constitutes a dispute, appeal and complaint, this "how to" guide identifies the kinds of problems that most commonly occur. It provides advice on how to overcome disagreements, file appeals and register complaints and, just as essential, where to direct them. This handbook also explains how to obtain higher-level review of regulatory actions and scientific disputes, and offers listings of relevant publications, contact persons, and mailing and electronic communication addresses that relate to the great majority of grievances.

Although this publication describes the formal processes that exist to enable aggrieved parties to communicate their differences or problems to the FDA, and to CDRH in particular, these processes should not supplant, nor are we discouraging, direct and less formal communications via letter, phone, or e-mail.

For our part, I pledge to work cooperatively with concerned parties to ensure that procedural rights are observed while seeing that decisions - both ours and yours - produce scientifically sound results for the American public. To that end, I hope you find this handbook useful.



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

Introductory Note

Medical Device Appeals and Complaints
Guidance on Dispute Resolution

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

Office of the Center Director
February 1998

Comments and suggestions may be submitted at any time for Agency consideration to **James Norman, HFZ-10.** Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact James Norman at 301-827-4380.

Additional Copies:World Wide Web/CDRH home page at http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 396 when prompted for the document shelf number.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

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SECTION I:

Overview of CDRH/FDA Dispute Resolution Processes

Overview of CDRH/FDA Dispute Resolution Processes

Persons who disagree with a CDRH/FDA decision or action and wish to have it reviewed and reconsidered have a broad array of dispute resolution processes from which to choose. In this section, these processes -- most of which FDA has established by regulation and appear in Title 21 of the Code of Federal Regulations (CFR) -- are grouped according to the degree to which formal procedures must be followed. Keep in mind as you read over this material that for any situation, multiple resolution processes may be available. It is up to the party seeking dispute resolution to determine which mechanism is most appropriate for a given circumstance or issue.

PRIMARY PROCESSES (LESS FORMAL)

- **21 CFR Part 10 - Administrative Practices and Procedures**

This section of the CFR outlines the practices and procedures for internal review, petitions and hearings that are typically used for resolving disputes and complaints. Part 10 provides multiple routes of appeal that may be used for actions not covered by the other Parts listed in this summary, or in some cases may be used as an alternative to other means of appeal, e.g., internal Agency review of decisions (21 CFR 10.75), citizen petition (21 CFR 10.30), and petition for reconsideration (21 CFR 10.33).

Internal Agency review of decisions - 21 CFR 10.75.

Internal Agency review through the supervisory chain is usually the quickest and most efficient means of resolving a dispute or appeal relating to a CDRH decision. Through this process, the supervisor of a Center employee will, at the request of an interested or aggrieved party, review a decision or action of the employee. An internal review may be requested for any decision that adversely affects the party making the request.

Normally, only CDRH personnel participate in the internal review. No public hearing is provided; however, at the supervisor's discretion, the party who requested the review may be invited to meet with Center personnel to discuss the matter.

If the party who requested an internal review is still dissatisfied following the review, the party may request an additional internal review further up the supervisory chain. Alternatively, the dissatisfied party may pursue one of the other dispute resolution / appeal processes, such as administrative reconsideration of action, a citizen petition, or one of the more formal processes.

Requests for internal CDRH review of an action are ordinarily required to be in writing. All requests should clearly identify the action for which review is being sought and should provide an explanation of the reason(s) for the review request. It is also helpful to provide the name, address, phone number and electronic mail address of a contact from whom additional information can be obtained if necessary.

Internal reviews must, by, regulation, be based on information in the official administrative file. If new information not in the file is provided in the request for review, the matter will not be treated as a request for review of a decision, but will instead be returned to the original decision-maker for reconsideration.

Filing a citizen petition - 21 CFR 10.30.

A citizen petition can be used by any person to appeal any FDA action or decision. Such petitions must conform to a specific format and must provide certain information. These requirements are explained in detail at 21 CFR 10.30 and 10.20 and should be carefully reviewed before preparing and submitting a petition. Among the informational items that must be included are:

- a citation of the statutory provisions upon which the petition is based (if known);
- a complete description of the action requested, including the exact wording of any proposed regulation or order;
- a statement of the factual and legal grounds for taking the requested action;
- information on any environmental impact; and

- certification that the petition includes the full information and views relied upon.

FDA may also request information on the economic impact of the requested action if it appears it would result in significant effects.

A citizen petition must be filed with FDA's Dockets Management Branch at the following address:

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
12420 Parklawn Drive (HFA-305)
Room 1-23
Rockville, MD 20857

Filing a petition for administrative reconsideration - 21 CFR 10.33.

A petition for administrative reconsideration can be used by any person to appeal any FDA action or decision. The petition must be filed within 30 days of the decision involved. A petition submitted later will ordinarily be denied as untimely, although the FDA Commissioner has discretion to permit a petition to be filed after 30 days when there is good cause to do so.

A petition for administrative reconsideration must conform to a specific format and must provide certain information. These requirements are explained in detail at 21 CFR 10.33 and 10.20 and should be carefully reviewed before preparing and submitting a petition. The petition must include:

- a statement of the decision to be reconsidered;

- the action FDA should take if the petition is granted; and

- the legal and factual grounds relied upon, including identification of relevant information and views that the petitioner contends were previously or adequately considered when CDRH made its decision.

No new information or views can be submitted in a petition for administrative reconsideration. The petition must be based *exclusively* on information in the administrative record on which the decision was made.

- A petition for administrative reconsideration will be granted *only* if FDA finds *all* of the following criteria have been met:

- the petition demonstrates that relevant information or views in the administrative record were not previously or not adequately considered when CDRH made its decision;

- the action requested is not frivolous and is sought in good faith;

- the petition demonstrates sound public policy grounds for reconsideration; and

- reconsideration is not outweighed by public health or other public interests.

A petition for administrative reconsideration must be filed with the Food and Drug Administration's Dockets Management Branch.

▸ IDE Review Committee

If a disputed issue involves an Investigational Device Exemption application or pre-IDE submission discussions, a sponsor / applicant can seek to have the issue reviewed by the IDE Review Committee. The Committee is comprised of the CDRH Director and the ODE Director, Deputy ODE Directors, ODE Division Directors and Deputy Directors and the IDE Staff.

The Committee has a two-fold charge: first, to serve as an internal quality control mechanism by reviewing randomly-selected IDE decisions to promote appropriate scientific content as well as consistency with FDA regulations and policies; and second, to afford IDE sponsors, who do not wish to seek formal reconsideration of an IDE-related decision through a Part 16 hearing (described later in this section), to have the decision considered by senior Center management. Meetings of the Committee are closed to the public because discussions invariably deal with confidential commercial information.

Requests for Committee review should include the device name and IDE application number, and must be received at least 30 days before one of the regularly scheduled quarterly meetings which are held in March, June, September and December of each year. Requests should be directed to:

Director
Investigational Device Exemption Program
Office of Device Evaluation
Center for Devices and Radiological Health
9200 Corporate Boulevard (HFZ-403)
Rockville, MD 20850

Depending upon the number of requests received, not all may be reviewed by the Committee at a given meeting. If the status of the IDE changes as a result of the Committee's review, the IDE sponsor will be notified by the appropriate ODE division within 30 days of the Committee's decision.

- **42 CFR Part 498 - Reconsideration of Adverse Decisions on Mammography Facility Accreditation/Certification**

Under the Mammography Quality Standards Act (42 U.S.C. § 263b), all U.S. medical facilities offering mammographic services must meet certain national operating standards and be "certified" by FDA following accreditation by an accreditation body (AB), which in turn has been approved by FDA. Any facility that has been denied accreditation is entitled to appeal the decision directly to the AB that rendered the decision. If the appellant facility cannot achieve satisfactory resolution of an adverse accreditation decision through a direct appeal to the AB, it may request reconsideration of the adverse decision by the Division of Mammography Quality and Radiation Programs at the address shown below. Any such request for reconsideration must be submitted within 60 days of an adverse appeals decision by the AB. Also, during the appeals process and reconsideration period, the appellant facility is not permitted to provide mammography services.

A request for reconsideration should be directed to:

Division of Mammography Quality and Radiation Programs
Attention: Standards Branch
Office of Health and Industry Programs
Center for Devices and Radiological Health
1350 Piccard Drive (HFZ-240)
Rockville, MD 20850

Included with a reconsideration request must be the AB's original denial of accreditation (including clinical or phantom image score sheets, when applicable), all information submitted by the facility to the AB relevant to the appeal (including all original films submitted to the AB), a copy of the AB's adverse appeals decision (including clinical or phantom image score sheets, when applicable), and a statement of the bases for the facility's disagreement with the AB's decision.

Within 60 days after receipt of a reconsideration request, the Division of Mammography Quality and Radiation Programs will render a decision and notify the facility in writing of the decision and the facility's options as a consequence of the decision. A facility that is dissatisfied with the Division's decision following reconsideration is entitled to a formal hearing before the Departmental Appeals Board, Department of Health and Human Services (see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III).

Copies of the applicable regulations governing such hearings (Subpart D, 42 CFR, Part 498) are available from the U.S. Government Printing Office. They may also be purchased via the Internet on a CD-ROM (titled "HCFA's Laws, Regulations, Manuals) at: http://www.access.gpo.gov/su_docs/sale/sale300.html, or may be found and downloaded by accessing the CFR on the Internet at: http://www.access.gpo.gov/nara/cfr/index.html, and searching CFR titles and volumes.

A facility that wishes to challenge an order suspending or revoking an FDA certificate that was issued under authority of the MQSA must do so in a Part 16 hearing (discussed later in this section and in the tables in Section II).

- **21 CFR Part 3 - Review of Product Jurisdiction**

This section of the CFR details the procedures for determining the Agency component with primary jurisdiction for premarket review and regulation of combination products. A determination centers chiefly on the primary mode of action of the product. Questions sometimes arise regarding how a product, whose components involve a combination of drugs, biologicals and medical devices, is to be regulated. Often such questions can be easily resolved at the program level - - in the case of medical devices, through the CDRH Jurisdiction and Device Status Expert. In some instances, however, the advice offered by CDRH may be disputed, in which case a higher level of review is available from FDA's designated product jurisdiction officer, the Chief Mediator and Ombudsman.

OTHER PROCESSES (MORE FORMAL)

The processes that follow can be procedurally rigorous and are often more time-consuming even though they may be the most appropriate in a specific circumstance.

- **21 CFR Part 12 - Formal Evidentiary Public Hearing**

A formal evidentiary hearing is the administrative equivalent of a civil court hearing and involves comparable preparation and procedural controls. Such hearings are provided only when specifically provided by law or when ordered by the FDA Commissioner. Section 21 CFR 10.50 lists provisions that afford an opportunity for a formal evidentiary hearing, and includes § 515(g) of the Federal Food, Drug and Cosmetic Act governing premarket approval applications (PMAs) and product development protocols (PDPs).

- **21 CFR Part 13 - Public Hearing Before A Board of Inquiry**

A hearing under Part 13 is called at the discretion of the FDA Commissioner, when specifically authorized by regulation, or as an alternative to a formal evidentiary public hearing. The purpose of such a hearing is to review medical, scientific and technical issues; the proceedings are conducted as a scientific inquiry and thus are not comparable to a legal trial.

- **21 CFR Part 14 - Public Hearing Before A Public Advisory Committee**

A hearing under Part 14 is called at the discretion of the FDA Commissioner, or when provided by law or regulations, or as an alternative to a formal evidentiary hearing. Hearings are provided under this Part for the:

- review of a performance standard for a radiation-emitting electronic product by FDA's Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC);
- classification of devices;
- establishment, amendment or revocation of a performance standard;
- review of a PMA or PDP ; and
- review of Quality System (formerly Good Manufacturing Practice) regulation.

- **21 CFR Part 15 - Public Hearing Before the FDA Commissioner**

A hearing under Part 15 is called at the discretion of the Commissioner, or when provided by law or regulation, or as an alternative to a formal evidentiary hearing. These hearings provide for the review of :

- proposals to allow persons to order custom devices;
- proposed Quality System (formerly Good Manufacturing Practice) regulation;
- proposed exemptions from federal preemption of state and local device requirements (21 CFR 808.25(e)).

- **21 CFR Part 16 - Regulatory Hearing Before the Food and Drug Administration**

A hearing under Part 16 is called at the discretion of the FDA Commissioner when considering regulatory action, or when provided by law

or regulation. Many statutory and regulatory provisions provide an opportunity for a regulatory hearing, including:

- sections 520(g)(4) and (g)(5) of the Federal Food, Drug and Cosmetic Act, relating to disapproval of an Investigational Device Exemption, or notice of a proposed withdrawal of approval;

- 21 CFR 814.46(c) relating to withdrawal of approval of a PMA;

- an order suspending or revoking an FDA certificate issued to a U.S. mammography facility pursuant to the MQSA.

▸ 21 CFR Part 17 - Civil Money Penalty Hearing

This section of the CFR delineates the practices and procedures for hearings concerning administrative imposition of civil money penalties. These are formal hearings before an administrative law judge with formal procedures. Timely appeals of a judge's decision may be made by either party to the Departmental Appeals Board (DAB) in the Department of Health and Human Services. Following the decision of the DAB, a party may petition for judicial review, as provided by the statute governing the matter in dispute.

Selecting/Using Appropriate Dispute Resolution Processes

Primary Processes (Less Formal)

Internal CDRH Review Through the Supervisory Chain

21 CFR 10.75

Advantages:

- Least formal process.
- Available for all types of disputes and appeals.
- Usually the fastest way to obtain review of a CDRH action or decision.
- Provides a forum for private airing of views. All other processes are more public and permit other parties to provide views.

Disadvantages:

- Review must be based on information in the official administrative file.

Examples of Use:

- Review a 510(k) NSE decision.
- Challenge a request for additional information.

Citizen Petition

21 CFR 10.30

Advantages:

- No restriction as to when a petition may be submitted.
- Regulation requires FDA to answer petition within no more than 180 days.
- Petition may be supplemented without prejudice until a final ruling is made or the petition is referred for a hearing.

Disadvantages:

- Highly public process.
- No penalty if FDA fails to meet regulatory time frames

Examples of Use:

- Request a product be exempted from premarket notification under § 510(k).
- Change the status of a device from investigational to commercial.

Petition for Administrative Reconsideration of Action

21 CFR 10.33

Advantages:

- Criteria for granting reconsideration are defined by regulation.
- Ensures higher-level review of action.
- Formal record is maintained.

Disadvantages:

- Limited scope – applies only to reconsideration of final FDA actions.
- Petition normally must be submitted within 30 days of the date of the decision for which reconsideration is sought.

Examples of Use:

- A petition for reconsideration may be submitted in response to a PMA "not approvable" letter, 21 CFR 814.44(f), or an order denying approval of a PMA, 21 CFR 814.45(e).

Primary Processes (More Formal)

Petition for Administrative Stay of Action

21 CFR 10.35

Advantages:

- Criteria for granting stay are defined by regulation.

Disadvantages:

- Available only in limited circumstances defined by regulation.
- Petition normally must be submitted within 30 days of the date of the decision for which a stay is sought.

Formal Evidentiary Public Hearing

21 CFR Part 12

Advantages:

- Procedures are designed to ensure thorough examination of issues.

Disadvantages:

- Available only where specifically provided by law (*e.g.*, review of PMAs and PDPs) or where ordered by FDA.
- Detailed procedural rules.
- May require assistance of legal counsel.

Public Hearing Before a Public Board of Inquiry

21 CFR Part 13

Advantages:

- Inquiry limited to medical, scientific and technical issues only.

Disadvantages:

- Board is not subject to specific time frames for holding hearing or issuing its decision.

Public Hearing Before a Public Advisory Committee

21 CFR Part 14

Advantages:

- Procedures are designed to ensure review by independent, impartial panel.

Disadvantages:

- Called at discretion of FDA, or when provided by law or regulation, or as alternative to a formal evidentiary public hearing.

Public Hearing Before the FDA Commissioner

21 CFR Part 15

Advantages:

- Ensures high-level FDA review.

Disadvantages:

- Called at discretion of FDA, or when provided by law or regulation, or as an alternative to a formal evidentiary public hearing.

Regulatory Hearing

21 CFR Part 16

Advantages:

- Provides a public forum for presenting facts and views concerning dispute (may be closed in limited situations).

Disadvantages:

- Timing of hearing is a discretion of hearing office appointed by FDA.

SECTION II:

Guidance on Selecting and Using Appropriate Dispute Resolution Processes

SPECIFIC APPEAL PROCESSES/PRIMARY CONTACTS

The tables that follow attempt to catalog the various types of appeals and complaints that CDRH has handled, along with available dispute resolution processes for each category. The organizational contact for a given dispute resolution process will depend upon the nature of the appeal or complaint. To assist you in identifying the appropriate contact in a given instance, a list of contacts and mailing addresses is provided below, which corresponds to the bracketed letters in the tables.

[A] Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-1)
Room 100E
Rockville, MD 20850

[B] Director
Integrity, Committee and
Conference Management Staff
Office of Systems and Management
Center for Devices and Radiological Health
Food and Drug Administration
2098 Gaither Road (HFZ-17)
Room 261
Rockville, MD 20850

[C] Regulations Staff
Office of Health Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive (HFZ-215)
Room 240W
Rockville, MD 20850

[D] Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-400)
Room 110G
Rockville, MD 20850

[E] Advisory Panel Coordinator
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-400)
Room 110D
Rockville, MD 20850

[F] Premarket Notification Coordinator
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-404)
Room 120A
Rockville, MD 20850

[G] IDE Coordinator
Program Operations Staff
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-403)
Room 130F
Rockville, MD 20850

[H] Director
Office of Compliance
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road (HFZ-300)
Room 243
Rockville, MD 20850

[I] Director
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive (HFZ-500)
Room 300D
Rockville, MD 20857

[J] Division of Mammography Quality
and Radiation Programs
Attention: Standards Branch
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive (HFZ-240)
Rockville, MD 20850

SPECIFIC APPEAL PROCESSES (continued)

[K] Jurisdiction and Device Status Expert
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard (HFZ-404)
Room 120C
Rockville, MD 20850

[L] Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
12420 Parklawn Drive (HFA-305)
Room 1-23
Rockville, MD 20857

[M] Chief Mediator and Ombudsman
Food and Drug Administration
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857

[N] Office of Orphan Products Development
Food and Drug Administration
5600 Fishers Lane (HF-35)
Room 8-73
Rockville, MD 20857

[O] Associate Commissioner for Legislative Affairs
Office of External Affairs
Food and Drug Administration
5600 Fishers Lane (HFW-1)
Room 15-55
Rockville, MD 20857

[P] Health Care Financing Administration
Department of Health and Human Services
Attention: Ms. Hippler
7500 Security Boulevard
C4-04-05
Baltimore, MD 21244

SPECIFIC APPEAL PROCESSES PREMARKET EVALUATION ISSUES: PREMARKET NOTIFICATION	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
510(k) refuse to accept decision	Written appeal for review through ODE/CDRH supervisory chain [F]; or citizen petition [L]; or petition for administrative reconsideration [L]. (*see pp. 2-5*)
Request for additional information	
Not substantially equivalent decision	
Substantially equivalent decision	
New 510(k) requirement/device modification	
510(k) rescission	
510(k) statement	Written appeal for review through ODE/CDRH supervisory chain [F] (*see pg. 2*) .
510(k) summary	
Exemption from 510(k) or revocation of previous exemption	Citizen petition [L]; or petition for administrative reconsideration [L] (*see pp. 3-5).*

FOOTNOTE: Bracketed letters refer to the contact office to which an appeal should be directed (see pp. 14-15).

SPECIFIC APPEAL PROCESSES PREMARKET EVALUATION ISSUES: INVESTIGATIONAL DEVICE EXEMPTIONS+	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Refuse to accept decision	Written appeal for review through ODE/CDRH supervisory chain [G] (*see pg. 2).*
IDE and IDE supplement disapproval decision	Written appeal requesting review by IDE Review Committee [G] *(see pg. 5);* or written request for Part 16 hearing (21 CFR 812.30(c)) [C] (*see pg. 9).*
Withdrawal of IDE approval	Written request for Part 16 hearing [C] (*see pg. 9).*
HCFA reimbursement designation	Written request for review through ODE/CDRH supervisory chain [G] *(see pg. 2);* if unresolved, may appeal to HCFA [P].+ (Appeals on IDE decisions may only be submitted by IDE sponsors.)

+Consumer/patient inquiries regarding HCFA reimbursement for medical procedures in which investigational medical devices are used should be directed to HCFA, as follows:

Grant Bagley, M.D.
Director of Coverage and Analysis Group
Health Care Financing Administration
7500 Security Boulevard
C4-01-15
Baltimore, MD 21244

SPECIFIC APPEAL PROCESSES PREMARKET EVALUATION ISSUES: PRODUCT DEVELOPMENT PROTOCOL	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Appropriateness of PDP	Written appeal for review through ODE/CDRH supervisory chain [D]; if unresolved, then to CDRH Director [A] *(see pg. 2).*
Disapproval of protocol	
Revocation of protocol (2 steps)	1. Proposed revocation: Written request for Part 16 hearing before order is finalized [L] *(see pg. 9).* 2. Final revocation order: Written appeal must be filed as petition for administrative reconsideration within 30 days of an order: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] (*see pg. 8).* (NOTE: Only PDP applicants can appeal these actions.)
Declaration of completion of protocol	Written appeal must be filed as citizen petition [L] (*see pg. 3).*
Declaration of non-completion of protocol	Written appeal must be filed as petition for administrative reconsideration within 30 days after FDA notification: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] *(see pg. 8).* (NOTE: Only PDP applicants can appeal these actions.)
Revocation of declared completed protocol	

SPECIFIC APPEAL PROCESSES PREMARKET EVALUATION ISSUES: PREMARKET APPROVAL	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
PMA refuse to file decision (including PMA supplements)	Written request within 10 days after FDA notification for informal conference with ODE/CDRH supervisory chain [D]; if unresolved, then to CDRH Director (21 CFR 814.42(d)(2)) [A] (*see pg. 2).* (NOTE: Only PMA applicants may file appeals for non-filing decisions.)
Additional information request (including major/minor deficiency letters)	Written appeal for review through ODE/CDRH supervisory chain [D] (*see pg. 2).*
PMA approvable, not approvable and denial decision	Written appeal must be filed within 30 days after FDA notification as petition for administrative reconsideration: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] (*see pg. 8).* (NOTE: Appeals can be made only by PMA applicants.)
PMA approval order	Written appeal within 30 days of approval order requesting administrative reconsideration: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] (*see pg. 8).* (NOTE: Appeals may be made by any interested person.)
Temporary suspension of PMA or PMA supplement	Written request for Part 16 hearing [C] (*see pg. 9).*
Withdrawal of PMA approval (2-step process)	1. Proposed withdrawal: requires written request for Part 16 hearing [C] *(see pg. 9).* 2. Final withdrawal: requires written appeal filed as petition for administrative reconsideration within 30 days of an order: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [C] (*see pg. 9).*

SPECIFIC APPEAL PROCESSES PREMARKET EVALUATION ISSUES: HUMANITARIAN DEVICE EXEMPTION	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Humanitarian use device (HUD) designation and supplements	Written appeal for internal Agency review through supervisory chain directed to FDA's Office of Orphan Products Development [N] *(see pg. 2)*
Withdrawal of humanitarian use device designation	
HDE refuse to file decision (including HDE supplements)	Written appeal to ODE/CDRH Director within 10 days after FDA notification [D] *see pg. 2)*; if unresolved, then to CDRH Director (21 CFR 814.112) [A] *(see pg. 2).* (NOTE: Only HDE applicants may file appeals.)
Additional information request (including major/minor deficiency letters)	Written appeal through ODE/CDRH supervisory chain [D] *(see pg. 2).*
HDE approvable, not approvable and denial decision	Written appeal must be filed as a petition for administrative reconsideration within 30 days after FDA notification: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] *(see pg. 8).* (NOTE: Approvable and not approvable decisions and denials may be appealed by HDE applicants only.)
HDE approval order	Written appeal within 30 days of approval order requesting administrative reconsideration: petitioner may choose reconsideration by either FDA advisory committee or through a Part 12 hearing [L] (*see pg. 8).* (NOTE: Petitions may be made by any interested person.)
Temporary suspension of HDE or HDE supplement	Written request for Part 16 hearing [C] (*see pg. 9*).
Withdrawal of HDE approval (2-step process)	1. Proposed withdrawal: requires written request for Part 16 hearing [C] *(see pg. 9).* 2. Final withdrawal: requires written appeal filed as petition for administrative reconsideration within 30 days of an order: petitioner may choose reconsideration either FDA advisory committee or through a Part 12 hearing [C] (*see pg. 8).*

SPECIFIC APPEAL PROCESSES POST-MARKET SURVEILLANCE ISSUES	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Initiation or denial of device tracking exemptions and variances	Written request for review through OC/CDRH supervisory chain [H]; or written petition for administrative reconsideration [L] (*see pg. 2).*
MDR alternative reporting and exemptions	Written request for review through OSB/CDRH supervisory chain [I]; if unresolved, then to CDRH Director [A] (*see pg. 2).*
Required post-market surveillance study	
Safety Alert	

SPECIFIC APPEAL PROCESSES REGULATORY COMPLIANCE ISSUES (MEDICAL DEVICES)	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Administrative detention	Written request for Part 16 hearing within 5 days of FDA detention action [H] (*see pg. 9).*
Civil money penalties	Written appeal to OC/CDRH Director requesting Part 17 hearing by Administrative Law Judge [H] (*see pp. 10 and 30*); after hearing and Commissioner-level review/decision, appeal may be made to HHS Departmental Appeals Board (*see pg. 34).*
Export permit decision	Written appeal for review through OC/CDRH supervisory chain [H] (*see pg. 2).*
Import detention	Written appeal for review directed to Import Compliance Officer in applicable ORA field office; if unresolved, appeal made to District Director, then to Regional Food and Drug Director (*see pp. 2 and 27).*
Inspectional observations (including bioresearch monitoring)	First-line appeal during exit interview with ORA field investigators; written appeal to appropriate ORA field office; if unresolved, written appeal to OC/CDRH Director [H] (*see pp. 12 and 28).*
Product recall	Written request for Part 16 hearing [H] (*see pg.14).*
518 notification	Written appeal for review through OC/CDRH supervisory chain [H] (*see pg. 2).*
Product seizure	Once FDA/U.S. Attorney files a complaint in U.S. District Court, resolution of any relevant disputed matter rests with the Court.
Promotion and advertising actions	Written appeals/complaints should be directed to OC/CDRH Director [H]; if unresolved, then to CDRH Director [A] (*see pg. 2).*
Regulatory citation	Written request for a hearing under Section 305 of the FD&C Act [H].
Warning Letter	Written appeal to District Compliance Office in applicable ORA field office; if unresolved, appeal made to District Director, then to Regional Food and Drug Director, then to ORA Office of Enforcement/ Associate Commissioner for Regulatory Affairs (*see pp. 27-28*). If Warning letter originated from CDRH, appeal to OC/CDRH Director [H] or CDRH Director [A] *(see pg. 2).*

SPECIFIC APPEAL PROCESSES REGULATORY COMPLIANCE ISSUES (RADIOLOGICAL PRODUCTS)	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Denial of exemption from radiological health product performance standards Denial of plan to repurchase, repair or replace radiological electronic products Notification of defects/failure to comply with radiological product performance standards	Written request for review by OC/CDRH supervisory chain *(see pg. 2);* if unresolved, can request a Part 16 hearing [H] (*see pg. 9).*
Denial of variance from compliance with radiological product performance standards	Written request for review through OC/CDRH supervisory chain [H] (*see pg. 2).*

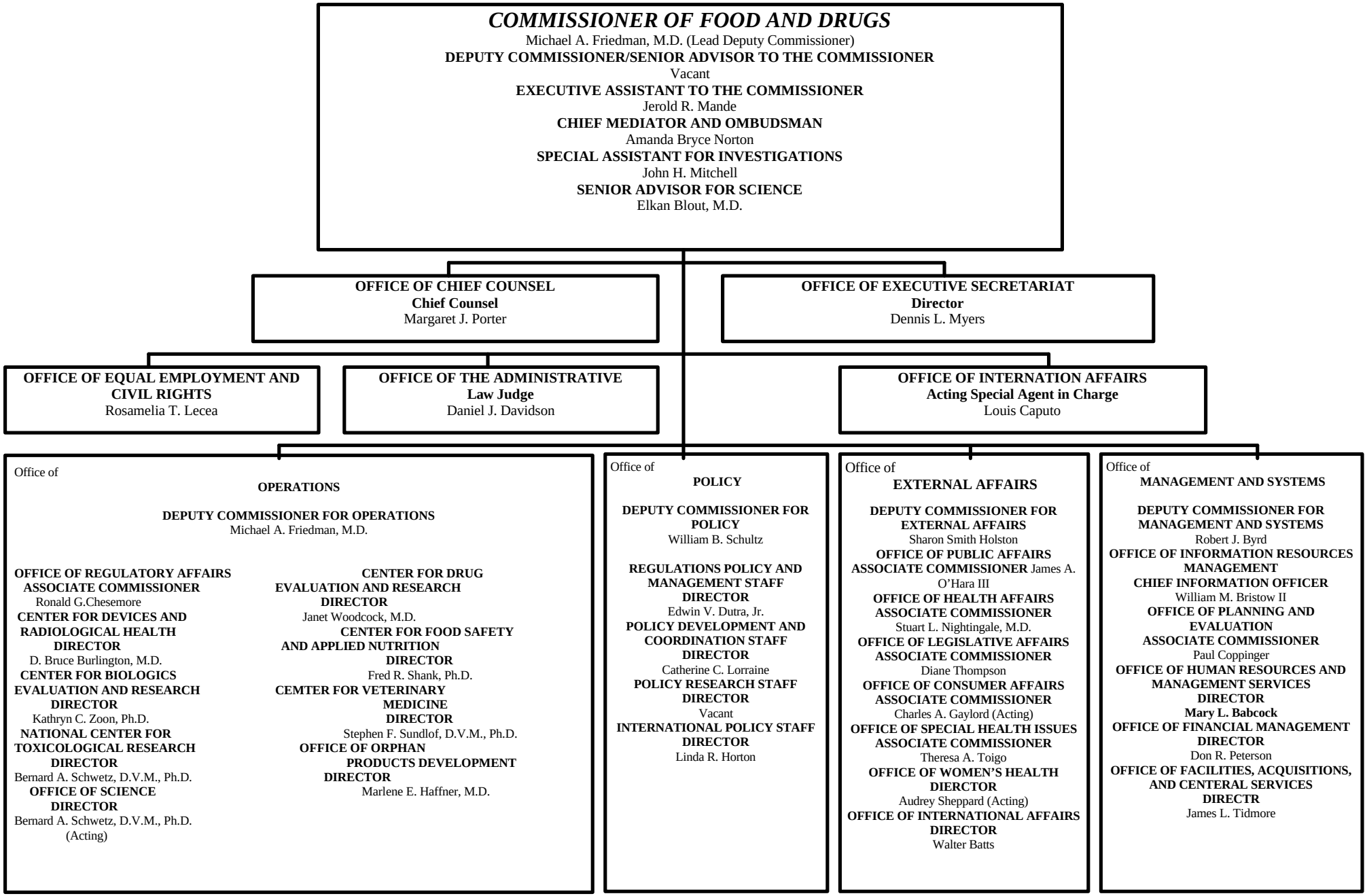
SPECIFIC APPEAL PROCESSES PRODUCT DESIGNATION ISSUES	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Combination products (product jurisdiction)	Written inquiries initially to CDRH Jurisdiction and Device Status Expert [K]; disputed decisions can be subsequently discussed with FDA Chief Mediator and Ombudsman [M] (*see pp. 2 and 30).*
Devices subject to FDA regulation	Written appeal to OC/CDRH Director [H] (*see pg. 2).*
Pre-Amendments status of devices	
Product classification/reclassification	

SPECIFIC APPEAL PROCESSES MISCELLANEOUS ISSUES	
Appeal/Complaint Type	**Dispute Resolution Process(es)**
Adverse decision on facility accreditation/ certification Mammography Quality Standards Act • Accreditation • Certification (suspension or revocation)	 • Written request for reconsideration to Division of Mammography Quality and Radiation Programs/Standards Branch/OHIP/CDRH [J]; review to occur in concert with ad hoc Facility Accreditation Review Committee *(see pg. 2)*. • Written request for a Part 16 hearing [C] *(see pg. 9)*.
Advisory panel meeting process/ procedure issues	Written statement to CDRH Advisory Panel Coordinator [E].
Potential conflict-of-interest issues: • CDRH/employees • Advisory panel members/consultants	 • Written statement to CDRH Integrity Officer [B]. • Written statement to CDRH Advisory Panel Coordinator [E].
CDRH employee misconduct	Written statement to CDRH Director [A]; or directly to FDA Office of Internal Affairs *(see pg. 33)*; or directly to HHS Office of Inspector General *(see pg. 35)*.
Congressional correspondence (constituent complaints directed to FDA by Members of Congress or Congressional committee chairs)	Letters should be directed to FDA's Office of Legislative Affairs [O].

SECTION III:

Reference Material

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINSTRATION (As of 1/98)



FDA Field Offices (As of 1/98)

FDA/FACSIMILE NETWORK

Regional/District Offices	FTS/ Commercial Number
NORTHEAST REGION	
NY Field Office	718-965-5759
NY Import Operations Br	718-965-5226
NY Regional Laboratory	718-965-5308
NY DISTRICT OFFICE	718-965-5117
Syosset Resident Post	516-912-2025
White Plains Resident Post	914-683-9702
Port Elizabeth Resident Post	201-351-7954
New York JFK Resident Post	718-917-0472
BUFFALO DISTRICT OFFICE	716-551-4470
Albany Resident Post	518-472-4501
Syracuse Resident Post	315-423-5576
Binghamton Resident Post	607-773-2608
Champlain Resident Post	518-298-5538
Newburgh Resident Post	914-567-1821
Rochester Resident Post	716-263-6286
BOSTON DISTRICT OFFICE	617-565-4709
Winchester Engr. Anal. Center	617-729-5700
Worchester Resident Post	508-793-0456
East Hartford Resident Post	203-240-4313
Augusta Resident Post	207-622-8273
Bridgeport Resident Post	203-579-5822
Concord Resident Post	603-225-1511
Essex Junction Resident Post	802-951-6240
Providence Resident Post	401-528-5399
MID-ATLANTIC REGION	
Philadelphia Field Office	215-597-6649
Philadelphia Investigation Br	215-597-0875
PHILADELPHIA DISTRICT OFFICE	215-597-8212
Montgomeryville Resident Post	215-362-0510
Pittsburgh Resident Post	412-644-5496
Wilmington Resident Post	302-573-6455
Harrisburg Resident Post	717-782-3834
Scranton Resident Post	717-342-8058
BALTIMORE DISTRICT OFFICE	410-962-2307
Baltimore Compliance Br	410-962-3792
Richmond Resident Post	804-771-2817
Arlington Resident Post	703-235-4330
Charleston Resident Post	304-347-5480
Morgantown Resident Post	304-291-4960
Roanoke Resident Post	703-982-4755
Norfolk Resident Post	804-441-3718
Salisbury Resident Post	301-860-1029
NEWARK DISTRICT OFFICE	201-331-3848
North Brunswick Resident Post	201-247-9818
Camden Resident Post	609-757-5311

Regional/District Offices	FTS/ Commercial Number
CINCINNATI DISTRICT OFFICE	513-684-6594
Cincinnati Laboratory	513-684-2905
Brunswick Resident Post	216-225-7477
Canfield Resident Post	216-533-4743
Columbus Resident Post	614-469-7359
Louisville Resident Post	502-582-5579
Toledo Resident Post	419-259-6353
SOUTHEAST REGION	
ATLANTA REGION OFFICE	404-347-4206
ATLANTA DISTRICT OFFICE	404-347-4206
Southeast Region Lab-Atlanta	404-347-4225
Charlotte Resident Post	704-371-6402
Columbia Resident	803-765-5680
Greensboro Resident Post	919-333-5563
Greenville, NC Resident Post	919-758-5007
Greenville, SC Resident Post	803-232-6783
Raleigh Resident Post	919-856-4776
Savannah Resident Post	912-944-4231
Tilton Resident	919-386-9610
ORLANDO DISTRICT OFFICE	407-648-6881
Miami Resident Post	305-526-2693
Tampa Resident Post	813-228-2483
Jacksonville Resident Post	904-791-2880
Tallahassee Resident Post	904-681-7697
NASHVILLE DISTRICT OFFICE	615-736-5435
Memphis Resident Post	901-544-3151
Birmingham Resident Post	205-731-1556
Chattanooga Resident Post	615-752-5111
Huntsville Resident Post	205-539-6344
Knoxville Resident Post	615-549-9327
Mobile Resident Post	205-690-2161
Montgomery Resident Post	205-223-7117
NEW ORLEANS DISTRICT OFFICE	504-589-6360
Baton Rouge Resident Post	504-389-0333
Gulfport Resident Post	601-863-1309
Jackson Resident Post	601-965-4581
Lafayette Resident Post	318-264-6603
Shreveport Resident Post	318-226-5343
San Juan District Office	809-729-6809
Mayaguez Resident Post	809-831-3339
MID-WEST REGION	
CHICAGO REGION OFFICE	312-886-1682
CHICAGO DISTRICT OFFICE	312-886-3280
Compliance Branch	312-353-0947
Chicago Laboratory	312-886-0967

Regional/District Offices	FTS/ Commercial Number
Gumee Resident Post	847-249-0175
Springfield Resident Post	217-492-4103
Peoria Resident Post	309-671-7199
Rockford Resident Post	815-987-4202
Hinsdale Resident Post	630-323-7137
Mt. Vernon Resident Post	515-781-5391
DETROIT DISTRICT OFFICE	313-226-3076
Indianapolis Resident Post	317-226-6506
Grand Rapids Resident Post	616-942-8756
Evansville Resident Post	812-465-6359
South Bend Resident Post	219-288-0737
Saginaw Resident Post	517-792-8859
Kalamazoo Resident Post	616-345-3203
Fort Wayne Resident Post	219-422-4062
MINNEAPOLIS DISTRICT OFFICE	612-334-4134
Minneapolis Compliance Br	612-334-4142
Sioux Falls Resident Post	605-330-4384
Madison Resident Post	608-264-5335
Milwaukee Resident Post	414-771-7512
Green Bay Resident Post	414-433-3949
Fargo Resident Post	701-239-5107
LaCross Resident Post	608-785-9951
SOUTHWEST REGION	
DALLAS REGION OFFICE	214-655-8130
DALLAS DISTRICT OFFICE	214-655-5331
Houston Resident Post	713-220-2327
Laredo Resident Post	512-726-2249
San Antonio Resident Post	512-229-4115
El Paso Resident Post	915-540-7696
Oklahoma City Resident Post	405-231-4543
Tulsa Resident Post	918-581-7627
Ft. Worth Resident Post	817-334-5219
Hidalgo Resident Post	512-843-2905
Austin Resident Post	512-482-5736
Lubbock Resident Post	806-743-7648
Ft. Smith Resident Post	501-646-6021
Little Rock Resident Post	501-378-5080
PACIFIC REGION	
DENVER DISTRICT OFFICE	303-236-3099
Salt Lake City Resident Post	801-524-6254
Albuquerque Resident Post	505-766-3478
Kansas City District Office	913-752-2136
St. Louis Branch	314-645-2969
Omaha Resident Post	402-331-9001
Des Moines Resident Post	515-284-7165
Sioux City Resident Post	712-252-0192
Springfield Resident Post	417-831-5058
Wichita Resident Post	316-269-7168
Cedar Rapids Resident Post	391-362-9155
Davenport Resident Post	319-326-3608

Regional/District Offices	FTS/ Commercial Number
SAN FRANCISCO DISTRICT OFFICE	415-556-2524
S.F. Compliance Branch	415-556-3486
Sacramento Resident Post	916-551-1087
San Jose Resident Post	408-291-7228
Honolulu Resident Post	808-541-2678
Chico Resident Post	916-342-8607
Fresno Resident Post	209-487-5321
Las Vegas Resident Post	702-388-6361
Reno Resident Post	702-784-5770
Stockton Resident Post	209-946-6021
LOS ANGELES DISTRICT OFFICE	714-798-7701
Los Angeles Compliance Br	714-798-7771
Los Angeles Airport	213-215-2373
Santa Ana Resident Post	714-836-2878
Phoenix Resident Post	602-640-2343
Terminal Island Resident Post	213-514-6114
San Diego Resident Post	619-550-3860
Tucson Resident Post	602-670-6730
San Bernardino Resident Post	714-383-5743
Calexico Resident Post	619-357-3656
Nogales Resident Post	602-287-5705
San Ysidro Resident Post	619-428-7216
Irvine Resident Post	714-836-2878
Santa Barbara Resident Post	805-687-4723
SEATTLE DISTRICT OFFICE	206-483-4996
Puget Sound Resident Post	206-442-7020
Portland Resident Post	503-326-5690
Anchorage Resident Post	907-271-5014
Blaine Resident Post	206-332-7771
Boise Resident Post	208-334-1820
Helena Resident Post	406-449-5212
Pocatello Resident Post	208-234-4963
Spokane Resident Post	509-353-2746
Yakima Resident Post	509-575-5925

FDA/HHS Dispute Resolution and Complaint Investigation Offices

- Administrative Law Judge, Food and Drug Administration

FDA's Administrative Law Judge (ALJ), whose office is organizationally located in the Office of the Commissioner, presides over all formal evidentiary hearings held by the Agency. The ALJ maintains procedural as well as administrative control of hearings, and issues decisions setting forth findings of fact and conclusions of law as to all issues involved in the hearings. General questions about the hearing process or specific hearing matters involving the ALJ should be directed to:

Administrative Law Judge
Food and Drug Administration
5600 Fishers Lane (HF-3)
Room 11-37
Rockville, MD 20857
Telephone: (301) 443-5315
Fax: (301) 594-6800

- Chief Mediator and Ombudsman, Food and Drug Administration

The Office of the Chief Mediator and Ombudsman deals with disputes and impasses arising out of the processes that have been established by all FDA Centers and field offices to implement their statutory mandates. The Office's goal is to facilitate a constructive resolution to disputed issues. The Office is neutral in that it has no vested interest in any particular outcome, but is a strong advocate for fair processes and fair outcomes.

The Office serves as a resource to regulated industry when disputes arise, such as concerns, for example, that FDA has not: determined the relevant issues; obtained accurate and complete information; applied relevant information properly; informed affected parties accurately and adequately; or revised past actions where appropriate. In addition, the Office serves as the Agency's focal point for product jurisdiction issues, pursuant to 21 CFR Part 3.

Although the Office believes that disputes should be resolved at the lowest organizational level whenever possible, the Office is available to all members of the regulated industry to listen and provide information, discuss and develop options, make referrals, look into problems, engage in informal third-party intervention and shuttle diplomacy, mediate issues, and take any other action necessary to facilitate a constructive resolution.

The Office's location at the Commissioner's level permits it to view issues dispassionately and exercise judgment independently. It is appropriate to contact this office when an issue involves more than one FDA center, or at any time when participation by an office outside the center would be useful.

Office of the Chief Mediator and Ombudsman
Food and Drug Administration
5600 Fishers Lane (HF-7)
Room 14-105
Rockville, MD 20857
Telephone: (301) 827-3390
Fax: (301) 594-6807

- Office of Criminal Investigations, Food and Drug Administration

The Office of Criminal Investigations (OCI) was authorized and established by the Secretary of Health and Human Services and is organizationally located in FDA's Office of Regulatory Affairs. The OCI serves as the criminal investigative arm of the FDA and conducts and coordinates all criminal investigations relating to violations of the Federal Food, Drug and Cosmetic Act and related Acts, the Federal Anti-Tampering Act, and applicable Title 18 offenses. Headquartered in FDA's main Rockville offices, OCI special agents are also stationed in six OCI field offices and four resident offices throughout the U.S. Persons with suspicions or information about or knowledge of possible criminal wrongdoing by a business enterprise that is regulated by FDA should contact the OCI at one of the offices shown below. Your contact will be confidential.

Headquarters

Office of Criminal Investigations
Office of Regulatory Affairs
Food and Drug Administration
7500 Standish Place (HFC-300)
Room 250N
Rockville, MD 20855-2773
Telephone: (301) 294-4030
Fax: (301) 594-1971

Field Offices

Food and Drug Administration
OCI Miami Field Offices
865 SW 78th Avenue (HFH-500)
Suite 201
Plantation, FL 33324
Telephone: (954) 476-5400
Fax: (954) 476-5435
(Covers AL, FL, GA, LA, MS, NC, SC and TN)

Food and Drug Administration
OCI Kansas City Field Office
Three Pine Ridge Plaza (HFH-510)
1901 W. 84th Terrace
Suite 201
Lenexa, KS 66214
Telephone: (913) 541-7400
Fax: (913) 541-7421
(Covers AR, CO, IA, KS, MO, NE, NM, UT and WY)

Food and Drug Administration
OCI San Diego Field Office
Pacifica Tower
4365 Executive Drive (HFH-520)
Suite 230
San Diego, CA 92122-2124
Telephone: (619) 550-2600
Fax: (619) 550-2627
(Covers AZ and So. CA)

Food and Drug Administration
OCI Chicago Field Office
901 Warrenville Road (HFH-530)
Suite 360
Lisle, IL 65032
Telephone: (630) 769-5520
Fax: (630) 769-5550
(Covers IL, IN, MN, ND, SD and WI)

Food and Drug Administration
OCI New York Field Office
10 Exchange Place (HFH-540)
Suite 804
Jersey City, NJ 07302
Telephone: (201) 547-3851
Fax: (201) 547-6309
(Covers CT, MA, ME, NH, No. NJ, NY, RI and VT)

Food and Drug Administration
OCI Washington Field Office
4041 Powder Mill Road (HFH-550)
Suite 200
Calverton, MD 20705
Telephone: (301) 902-1500
Fax: (301) 344-3465
(Covers DE, KY, MD, So. NJ, OH, PA, VA, WV and DC

- Office of Internal Affairs, Food and Drug Administration

The Office of Internal Affairs (OIA) was authorized and established by the Secretary of the Department of Health and Human Services, within the FDA's Office of the Commissioner, to conduct internal investigations of employee misconduct and to provide a centralized liaison between FDA and HHS' Office of Inspector General (OIG). The OIA is staffed by experienced criminal investigators and acts independently of any of the FDA Centers, FDA's Office of Regulatory Affairs and FDA's Office of Criminal Investigations. The OIA reports directly to the Deputy Commissioner/Senior Advisor to the Commissioner.

Under the oversight of and collaboration with the OIG, the OIA investigates allegations of misconduct and violations of laws by FDA employees, including but not limited to:

retaliation
obstruction of justice, perjury or bribery
conflict of interest
arrest of an FDA employee
mismanagement
unauthorized release of information
misconduct
embezzlement of government property and funds
time and attendance abuse
misuse of government property
theft
violations of travel regulations
falsifying information on official forms
impersonation.

Allegations of misconduct by FDA employees and alleged violations of federal laws and regulations are received by the OIA from FDA employees, FDA management officials, other components of DHHS, outside agencies and the public, including regulated industry. Allegations can be submitted in the form of letters, telephone calls, and personal visits by complainants. Allegations submitted in writing should be directed to the Special Agent in Charge at the address shown below.

Office of Internal Affairs
Food and Drug Administration
One Church Street (HF-9)
Suite 700
Rockville, MD 20850
Telephone: (301) 827-0243
Fax: (301) 827-0273

- Special Assistant for Investigations, Food and Drug Administration

The Special Assistant for Investigations oversees a separate unit in the Office of the Commissioner that is charged with a variety of investigative, strategic and communications responsibilities. OSI routinely communicates on behalf of the Commissioner with representatives of FDA-regulated industries, individual companies and individuals who have concerns or complaints regarding FDA management, procedures or regulatory decisions. In this role, OSI acts as an independent "troubleshooter" for the Commissioner and the Commissioner's office, and works closely with other agency investigative and operational units in order to resolve problems before they escalate into larger-scale disputes. Questions or concerns may be directed to:

Special Assistant for Investigations
Food and Drug Administration
5600 Fishers Lane (HF-5)
Room 15-44
Telephone: (301) 443-6955
Fax: (301) 443-5262

- Departmental Appeals Board, Department of Health and Human Services

The Departmental Appeals Board (DAB) is responsible for adjudicating appeals of civil penalties imposed under a wide range of new statutory authorities, including the Federal Food, Drug and Cosmetic Act, the Mammography Quality Standards Act, and other statutes. The DAB has four main divisions: Appellate, Civil Remedies, Medicare Operations and Alternative Dispute Resolution.

The division most relevant to disputes and complaints involving FDA is the Appellate Division, which primarily reviews "disallowances" in numerous

HHS grant programs. Also reviewed are decisions in cost allocation disputes, debarments, scientific misconduct cases (e.g., where a researcher is alleged to have falsified data) and civil remedies decisions, among others. Inquiries or disputes that are unresolvable first through FDA channels should be directed to:

Departmental Appeals Board
Department of Health and Human Services
Hubert H. Humphrey Building, Room 637D
200 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 690-5501
Fax: (202) 690-5863

For further information, refer to the DAB Website at: http://www.dhhs.gov (click on DHHS icon).

- Office of Inspector General, Department of Health and Human Services

The Office of Inspector General (OIG) operates as an independent entity within the Department of Health and Human Services and investigates waste, fraud and abuse allegations in connection with Medicare and Medicaid programs and other HHS programs. With respect to FDA specifically, the OIG's investigatory jurisdiction extends to violations of criminal law and federal regulations - - for example, contract and grant fraud, gross mismanagement, abuse of authority, systematic theft or abuse of government property or services, conflicts of interest, standards of conduct violations and kickbacks or bribery involving FDA employees. Often, the OIG works in tandem with FDA's Office of Internal Affairs on cases of mutual interest and where complementary investigative authorities and expertise are required.

The OIG can be contacted at the office number and mailing address provided below.

Office of Inspector General
Department of Health and Human Services
Wilbur J. Cohen Building
Room 5250
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-3148
Fax: (202) 619-0521

The OIG also maintains a “hot line” with English and Spanish-speaking operators for those who wish to make complaints anonymously.

- - Commercial: (410) 965-5953
- - Toll Free: 1-800-HOT-TIPS

For further information on the OIG, as well as instructions on where to direct a complaint, refer to the OIG’s Website at: http://www.dhhs.gov/progorg/oig.

SECTION IV:

Glossary of Terms

Glossary of Terms

Additional information request - A request by a medical device reviewer for supplementary or clarifying information in connection with a marketing application. (This term includes major and minor deficiency letters associated with premarket approval applications and additional information letters relating to premarket notification submissions.)

Adjudicate (Adjudication) - To make a final judgment in a lawsuit; the judgment of the court.

Administrative detention (See Detention).

Administrative hearing - A public hearing that focuses on oral presentation of evidence, with more relaxed procedures and more liberal admissibility of evidence than a formal evidentiary public hearing.

Administrative Law Judge (ALJ) - An employee of the Food and Drug Administration whose office resides in the Office of the Commissioner. The ALJ presides over evidentiary hearings concerning agency regulatory actions from which outside parties are seeking formal redress. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Advisory committee / panel - A group of experts from outside the Food and Drug Administration that is formally assembled to provide guidance on technical, scientific, clinical, regulatory and policy matters to agency managers and staff-level professionals.

Allegation - An assertion or statement, made in a pleading, setting forth what its maker intends to prove.

Appeal - A request by an aggrieved party to some higher level authority for reconsideration, sanction, corroboration or decision on a specific matter. Also, a formal review by a higher court of a lower court's disposition of a lawsuit.

Approvable - A determination made by a supervisor within the Food and Drug Administration that a particular application (generally a premarket approval application or humanitarian device exemption) can be approved if specific additional information is submitted or specific conditions are agreed to by the applicant.

Arbitration - The most traditional form of private dispute resolution, which can be administered by a neutral third-party or facilitator or by the disputing parties themselves.

> Binding arbitration - A private adversarial process in which disputing parties choose a neutral individual or panel of disinterested individuals to hear their dispute and reach a final or binding decision.
>
> Non-binding arbitration - A process that works in the same manner as binding arbitration except that the neutral party's decision is advisory only.

Burden of proof - The necessity or duty of proving a fact or facts in dispute on an issue. If the evidence produced by the party having the burden of proof is insufficient, the FDA or court will rule against the party.

CDRH employee misconduct - A broad term that encompasses questions or complaints about violations of policy or procedure, regulatory fairness, retaliatory actions, criminal activity, etc. on the part of any employee of the Center for Devices and Radiological Health that precludes a regulated entity from receiving fair treatment.

Center for Devices and Radiological Health (CDRH) - An organizational component within the Food and Drug Administration responsible for administering those aspects of the Federal Food, Drug and Cosmetic Act relating to medical devices and radiation-emitting electronic products.

Chief Mediator and Ombudsman - A person / office in the Food and Drug Administration's Office of the Commissioner responsible for resolving internally and externally-generated disputes involving program operations, policies and procedures. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Citation (see Hearing).

Citizen petition - A formal request or appeal submitted by an individual or entity to the Food and Drug Administration in accordance with sections 10.30 and 10.20 in Title 21 of the Code of Federal Regulations. A petition seeks a specified action by the agency in connection with particular regulatory matters.

Civil money penalty - A monetary fine levied against a business entity or individual found to be in violation of Federal Food, Drug and Cosmetic Act and/or companion regulations or other statutes enforced by the Food and Drug Administration.

Code of Federal Regulations (CFR) - A codification of the published rules in the Federal Register by the executive departments and agencies of the Federal government. The CFR is divided into 50 titles which represent broad areas subject to Federal regulation. Title 21 contains a compilation of Food and Drug Administration regulations that implement various statutory authorities and directives with which industries regulated by the agency must comply.

Combination product (also see Product jurisdiction) - A medical device that acts in combination with another product regulated by the Food and Drug Administration, e.g., an infusion pump that delivers a pharmaceutical to the human body. In such cases, the decision regarding how the product is regulated is determined by which component is the primary mode of action.

Complaint - An expression of dissatisfaction or discontentment with a decision or action.

Complainant - A person registering a complaint, e.g., a member of regulated industry complaining about a regulatory action or decision.

Denial - A determination by a supervisor within the Food and Drug Administration that a particular application (generally a premarket approval application or humanitarian device exemption) cannot be approved due to major deficiencies or failure on the part of the applicant to comply with Agency regulations.

Department of Health and Human Services (DHHS) - An organization in the Executive Branch headed by a Secretary with cabinet rank, in which the Food and Drug Administration is located.

Departmental Appeals Board (DAB) - The highest level forum within the Department of Health and Human Services in which appeals of certain FDA actions, notably the imposition of civil money penalties, are made and resolved. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Detention - An administrative action whereby the Food and Drug Administration requires that imported articles that appear violative under the laws FDA administers be held intact. Detained articles may be released if brought into compliance with or determined to be not subject to the Federal Food, Drug and Cosmetic Act, or refused entry if not brought into compliance.

Device tracking - A system that medical device manufacturers by law must maintain that enables them to locate patients who are exposed to particular devices, facilitating product recalls and other types of regulatory notifications.

Dispute - A disagreement between two parties that ordinarily involves a debate or argument over certain facts.

Dispute resolution - The process by which a mutually acceptable settlement is reached between two parties engaged in a dispute.

Division of Small Manufacturers Assistance (DSMA) - An organizational component within the Center for Devices and Radiological Health established by law for the purpose of providing direct assistance to businesses and individuals in complying with the Food and Drug Administration's medical device rules.

Evidentiary hearing - A formal public hearing with detailed procedural rules designed to ensure a thorough examination of an issue. An evidentiary hearing is similar to a trial and may involve briefs and oral arguments, depositions, testimony of witnesses (including cross-examination), motions, transcription of hearings and other formal procedures. A formal evidentiary hearing will be presided over by the ALJ, the FDA Commissioner, or a member of the Commissioner's staff.

Export - The shipment of articles from the U.S. to a foreign country. Articles that comply with the Federal Food, Drug and Cosmetic Act may be exported freely. Section 801(e)(10) currently contains the requirements for the export of articles that, but for intended export, would be adulterated or misbranded; Section 801(e)(10) also contains additional requirements applicable to the export of medical devices.

Export permit - Permission granted by the Food and Drug Administration to a business entity to sell, distribute or otherwise make available medical devices to a country other than the United States.

Food and Drug Administration (FDA) - An organizational component within the Department of Health and Human Services, which is headed by the Commissioner of Food and Drugs and is responsible for the regulatory oversight of human and veterinary drugs, biologicals, foods, cosmetics, medical devices and radiological products.

Grievance - A complaint or protest based on an actual or supposed circumstance which is regarded as just cause for remedial action.

HCFA reimbursement designation - A process used to decide whether an investigational device would be considered reimbursable under Medicare and Medicaid. Decisions ordinarily rest on whether a device is a breakthrough product or is similar to one about which the safety and effectiveness characteristics are well established.

Health Care Financing Administration (HCFA) - An organizational component within the Department of Health and Human Services, which is headed by an Administrator and is responsible for administering a number of nationwide programs, including Medicare and Medicaid.

Hearing - The opportunity for a party to present views. A hearing prior to consideration of criminal proceedings, for example, is provided pursuant to section 305 of the Federal Food, Drug and Cosmetic Act. Many types of administrative hearings are provided for in various sections of the Code of Federal Regulations.

Humanitarian use device designation (HUD) - A medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

Humanitarian Device Exemption (HDE) - An application for marketing approval for a limited patient population (‹4000 patients in the U.S. per year). For this type of application, safety and probable benefit as opposed to safety and effectiveness of a device (as in a premarket approval application must be demonstrated.

Import - A product brought into the United States from a foreign country. Such products include American manufactured goods that are being returned to the U.S. Once such products are admitted by the Food and Drug Administration and the bond is liquidated by U.S. Customs, they are no longer considered to be in import status. Under certain limited conditions, released articles may be reverted back to import status.

Import detention - A "hold" imposed by the Food and Drug Administration on the importation of a medical device into the United States because the article appears to be in violation of the law.

Integrity Officer - A person in the Center for Devices and Radiological Health who is charged with overseeing conflict-of-interest issues as they relate to Center employees and members of medical device and radiological product advisory committees and panels.

Investigational Device Exemption (IDE) application - An application submitted under the provision of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act that sets forth certain regulatory requirements and exemptions for the conduct of clinical investigations of devices. An approved IDE allows product sponsors and clinical investigators to use unapproved medical devices in certain clinical trials.

Market Withdrawal - A firm's removal or correction of a distributed product that involves a minor violation for which FDA would not initiate legal action, or that involves no violation. Replacement of device components that fail after a reasonable lifespan will be considered a market withdrawal unless a violation of the Federal Food, Drug and Cosmetic Act has occurred and can be supported. Also, the removal of products from the market as a result of actual or alleged tampering with individual unit(s), and where there is no evidence of manufacturing or distribution problems, will be considered a market with-drawal.

Mediation - A voluntary and informal process in which disputing parties select a neutral third party to assist in reaching a negotiated settlement.

Medical Device Reporting (MDR) (also alternative reporting and exemption) - A provision of the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act that sets forth certain requirements for the reporting by medical device manufacturers of device-related incidents. The law was amended in 1990 to expand the reporting requirements to various types of medical device user facilities and distributors of medical devices. Food and Drug Administration regulations allow entities to use alternative forms of reporting, such as reporting via electronic media, and to receive an exemption from reporting under certain circumstances.

Non-filing - A decision made by the Office of Device Evaluation after an initial "screen" of an incoming marketing application (generally a premarket approval application or humanitarian device exemption) to reject the submission due to incompleteness or for other reasons. Once a non-filing decision is made, no further scientific evaluation is accorded the application.

Not approvable - A determination made by an FDA supervisor that a particular application (generally a premarket approval application or humanitarian device exemption), due to deficiencies in form or substance, cannot be approved in its present state.

Office of Device Evaluation (ODE) - An organizational component within the Center for Devices and Radiological Health that evaluates marketing applications for medical devices.

Office of Compliance (OC) - An organizational component within the Center for Devices and Radiological Health that is responsible for overseeing regulatory compliance by medical device and radiological product manufacturers with applicable laws and regulations, in addition to managing enforcement actions against violators.

Office of Criminal Investigations (OCI) - An organizational component within the Food and Drug Administration's Office of Regulatory Affairs that is responsible for investigating allegations of criminal wrongdoing within industries regulated by FDA. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Office of Inspector General (OIG) - An independent organization in the Department of Health and Human Services that is responsible for investigating allegations of fraud, abuse and waste involving HHS programs, as well as auditing internal programs for material weaknesses and other problems. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Office of Internal Affairs (OIA) - An organizational component within the Food and Drug Administration that investigates allegations of a wide range of matters relating to employee misconduct. The OIA reports to the Deputy Commissioner / Senior Advisor to the Commissioner. (For more information, see **FDA/HHS Dispute Resolution and Complaint Investigation Offices** in Section III.)

Office of Legislative Affairs (OLA) - An organizational component within the Food and Drug Administration that serves as the primary interface with the United States Congress on legislative and program oversight matters. OLA is the first-line recipient of complaints from congressional members and committees on behalf of FDA-regulated businesses and individuals.

Office of Regulatory Affairs (ORA) - An organizational component within the Food and Drug Administration that manages and coordinates all field enforce-ment and inspectional activities throughout the country. ORA also houses the Office of Criminal Investigations (referred to above).

Office of Surveillance and Biometrics (OSB) - An organizational component within the Center for Devices and Radiological Health that is responsible for overseeing and managing various post-market vigilance programs to ensure the continued safety and effectiveness of medical devices and radiological health products in commercial use.

Ombudsman - A person who provides an organizational dispute resolution mechanism by investigating complaints within the organization and either prevents disputes or facilitates their resolution.

Petition for administrative reconsideration - A formal request by a person or entity affected by or with an interest in an action taken by the Food and Drug Administration. Such a request must be made in accordance with certain information requirements set forth in section 10.33 in Title 21 of the Code of Federal Regulations.

Pre-Amendments status - A determination made by the Center for Devices and Radiological Health as to whether a particular medical device or a particular intended use for a device that existed prior to enactment of the Medical Device Amendments of 1976. Ordinarily, a determination is made on the basis of documentary evidence (e.g., affidavits, purchasing and distribution records, etc.) furnished by a medical device manufacturer, distributor, importer or other business entity.

Premarket approval (PMA) - A marketing application for medical devices that pose a high risk to humans or have otherwise been classified in class III. Applicants must provide reasonable assurance that the device is safe and effective for its intended use.

Premarket notification (510(k)) - A marketing application for medical devices that requires manufacturers to demonstrate substantial equivalence of their products to another device on the market prior to 1976 or to a device distributed after 1976 that has been found substantially equivalent to a pre-1976 predicate.

> "Refuse to accept" decisions - An indication that an application is insufficiently complete to allow substantive review by the Food and Drug Administration (this term can also apply to IDEs).

- Substantially equivalent / not substantially equivalent - A finding by the Food and Drug Administration that a device is or is not "substantially equivalent," as that term is defined in section 513(i) of the Federal Food, Drug and Cosmetic Act, to a product on the market prior to May 28, 1976 or to a product marketed after that date which itself has been found equivalent to a pre-1976 device.

  510(k) rescission - An action by the Food and Drug Administration to revoke a substantially equivalent determination based upon new information affecting the original determination or demonstrating a health hazard posed by the medical device. The effect of a rescission is a prohibition on further commercial distribution of the device until certain corrective or administrative actions are taken.

  510(k) statement - A certification that all information regarding safety and effectiveness in a 510(k) will be made available within 30 days of a request for such information. Such statements, or alternatively 510(k) summaries, are a required element of 510(k)s.

  510(k) summary - A summary of any information respecting safety and effectiveness. Such summaries, or alternatively 510(k) statements, are a required element of 510(k)s.

Product Development Protocol (PDP) - A prospectively defined plan in which the preclinical and clinical testing required for device approval is specified and agreed to by the applicant and the Food and Drug Administration.

Product jurisdiction - See Combination product.

Radiological product (also radiation-emitting electronic product) - An electronic product that is capable of producing ionizing or non-ionizing radiation and is subject to Federal rules promulgated under the Radiation Control for Health and Safety Act of 1968.

Recall - A firm's removal or correction of a marketed product or products, including its labeling and promotional materials, that the Food and Drug Administration considers to be in violation of the laws it administers, and against which the agency would initiate legal action. Recall does not include a market withdrawal or a stock recovery.

  FDA Ordered Recall - A recall initiated by a firm in response to an order for such action, e.g., medical device recalls ordered under section 518(e) of the Federal Food, Drug and Cosmetic Act.

FDA Requested Recall - A recall initiated by a firm in response to a formal request for such action by the Food and Drug Administration's Associate Commissioner for Regulatory Affairs or the appropriate center director when the authority has been delegated.

> Firm Initiated Recall - A recall that is initiated by a firm on its own volition without a formal request from the Food and Drug Administration.

"Refuse to file" decision - An indication that an application (generally a premarket approval application or investigational device exemption) is insufficiently complete to allow substantive review by the Food and Drug Administration.

Repair, Replace or Refund (518 notification) - A provision of the Medical Device Amendments of 1976 that authorizes the Food and Drug Administration to require medical device firms to "repair, replace or refund" in cases when devices are found to be defective and to pose a serious threat to the public health.

Required post-market surveillance studies - Studies of certain marketed medical devices (most often, categories of devices) that are mandated by the Food and Drug Administration under authority of section 522(a)(1) of the Federal Food, Drug and Cosmetic Act and which are intended to provide vital information on the safety and performance of products over prescribed periods of time.

Safety Alert - A formal communication from the Center for Devices and Radiological Health to users of a particular medical device or category of devices that have been shown to pose a health threat to patients, users, or both. A Safety Alert provides safety warnings and/or preventative guidance.

Seizure - Attachment of goods through court order by a U.S. Marshal pursuant to section 304 of the Federal Food, Drug and Cosmetic Act.

Special Assistant for Investigations - A person in the Food and Drug Administration who conducts targeted investigations into reported operational problems and counsels the Commissioner and other senior FDA managers on issues raised by complainants from regulated industry, the health professional community and the consumer community, among others. The Special Assistant for Investigations reports directly to the FDA Commissioner.

Supplement - A supplemental application to an approved premarket approval application or humanitarian device exemption requesting approval for a change or modification to a device. IDE supplements are submitted for changes such as modifications to an investigational plan, study size and device design.

Temporary suspension - An action authorized by the Federal Food, Drug and Cosmetic Act and taken by the Food and Drug Administration that may, temporarily, suspend an approved premarket approval application when the agency finds the device may cause serious adverse health consequences or death. FDA must provide an opportunity for an informal hearing before suspending a PMA. When a PMA is suspended, commercial distribution of the device must cease and FDA will proceed to formally withdraw approval of the PMA.

Warning Letter - A written communication from FDA notifying an individual or firm that the agency considers one or more products, practices, processes or other activities to be in violation of the Federal Food, Drug and Cosmetic Act, or other laws or regulations, and that failure of the responsible party to take appropriate and prompt action to correct and prevent any future recurrence of the violation may result in administrative and/or regulatory enforcement action without further notice.

Withdrawal of Market Approval/Clearance - The revocation of marketing approval or clearance that had been granted by FDA. Such action is normally associated with a violation of the Federal Food, Drug and Cosmetic Act and/or a risk to public health.