Resolving Scientific Disputes Concerning The Regulation Of Medical Devices, A Guide To Use Of The Medical Devices Dispute Resolution Panel; Final Guidance for Industry and FDA

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This document supersedes the Draft Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Administrative Procedures on Use of the Medical Devices Dispute Resolution Panel, April 27, 1999

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director

Foreword

The Food and Drug Administration Modernization Act of 1997 (FDAMA) introduced many significant changes to the regulation of medical devices. As a result of these changes, FDA and the medical device industry should be better able to meet the public's need for innovative, safe, and effective health care products, and the U.S. device industry will be better able to compete in the global marketplace.

Section 404 of FDAMA added a new statutory provision on dispute resolution. The new provision, section 562 of the Food, Drug, and Cosmetic Act, is designed to ensure that FDA makes appropriate use of independent scientific experts to advise the agency on "scientific controversies" between FDA and a sponsor, applicant, or manufacturer. The Center for Devices and Radiological Health (CDRH) is implementing section 562 by establishing a new advisory Panel, the Medical Devices Dispute Resolution Panel, instituting a Center Ombudsman, and providing this guidance on use of the new Panel.

I am pleased that CDRH is providing these additional tools to contribute to the timely and fair resolution of scientific disagreements. Sponsors, applicants, and manufacturers can now make use of a wider range of dispute resolution mechanisms, including both formal and informal processes. With good will on both sides, it should be possible to quickly and fairly resolve any dispute.

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Preface

Public Comment

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

For questions regarding the use or interpretation of this guidance contact Les Weinstein at 301-827-7991 or by email to ombudsman@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at:
http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html
or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1121 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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Resolving Scientific Disputes Concerning The Regulation of Medical Devices

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

A. Introduction

The Food and Drug Administration (FDA) and its Center for Devices and Radiological Health (CDRH) are constantly striving to improve the efficiency and effectiveness of our regulatory processes. One area that is receiving heightened attention is the need to ensure effective processes for resolving scientific disputes that arise between FDA and the medical device industry.

FDA offers a wide array of dispute resolution mechanisms through which the device industry can obtain reconsideration of FDA decisions and actions.[1] Recently the position of CDRH Ombudsman was created to assist persons at any stage of a dispute with FDA regarding medical devices in a timely, impartial and fair manner. The Food and Drug Administration Modernization Act of 1997 (FDAMA) reinforced the importance of dispute resolution by enacting a new provision[2], section 562 of the Food, Drug, and Cosmetic Act (FD&C Act), which directs FDA to ensure it has effective processes by which a medical device "sponsor, applicant, or manufacturer" can obtain independent review of a "scientific controversy" between that person and FDA.

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[1] These processes are summarized in *Medical Device Appeals and Complaints — Guidance on Dispute Resolution*, available from CDRH.

2 Section 404 of FDAMA

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To implement the new provision, FDA amended 21 C.F.R. § 10.75 to clarify the availability of review of scientific disputes by an advisory Panel of experts when circumstances warrant. CDRH, in turn, has created a new advisory Panel, the Medical Devices Dispute Resolution Panel, which will operate under FDA's Medical Devices Advisory Committee.

B. Purpose

In keeping with FDA's Good Guidance Practices policies and procedures[3], this document sets forth guidelines that will govern the operation of the Medical Devices Dispute Resolution Panel. Although it represents FDA's current thinking on the most effective methods to resolve scientific disputes concerning medical devices, this document is intended only to provide general guidance. In response to comments on the draft version of the guidance from the medical device industry, we have revised the document to increase the independence and timeliness of the Dispute Resolution Panel process and to clarify the kinds of scientific disputes the Panel may review.

In addition to serving as a useful forum in which scientific disputes in general can be aired, the establishment of the Medical Devices Dispute Resolution Panel implements four provisions of the FD&C Act:

- **Section 514(b)(5)** requires the establishment of an advisory committee to take referrals of any matter which requires the exercise of scientific judgment involved in a proposed regulation to establish, amend, or revoke a performance standard.

- **Section 515(g)(2)(B)** requires the establishment of an advisory committee to take referrals of petitions for review of the approval, denial, or withdrawal of approval or a premarket approval application (PMA), or the revocation of an approved product development protocol (PDP), a declaration that an approved

[3] 65 FR 56468 (September 19, 2000)

PDP has not been completed, or a revocation of an approved Notice of Completion that permitted marketing of a device developed under a PDP.

- **Section 522(b)** of the act[4] requires a process to resolve any disputes concerning the need for FDA to order a manufacturer to conduct postmarket surveillance for more than 36 months.

- **Section 562** of the act[5] requires FDA to provide a procedure for review of all scientific disputes regarding the regulation of medical devices, including review by an appropriate scientific advisory Panel, but only to the extent that other provisions of the act or FDA regulations do not already provide a right of review. FDA believes its current procedures already provide methods to obtain review of most, if not all, scientific disputes. The establishment of the Dispute Resolution Panel provides an additional, more focused, procedure for the timely review of scientific disputes.

This guidance will not be applied to interfere with any statutory right to immediately request review of a matter pursuant to §§ 514(b)(5)(A)(ii), 515(g)(2)(A), 522(b), or 562 of the FD&C Act. A person who wishes to immediately invoke a right of review provided by one of these provisions should contact the CDRH Ombudsman.

[4] This provision was added by § 212 of FDAMA.

[5] This provision was added by § 404 of FDAMA.

C. Definitions

CDRH Ombudsman — a person appointed by and reporting directly to the Director, CDRH, who provides information and advice on dispute resolution mechanisms, serves as the primary contact for a particular dispute, provides staff support for the Medical Devices Dispute Resolution Panel, and may assist in the mediation of disputes. If more than one dispute is under review at a particular time, the CDRH Ombudsman may designate a senior level employee to act as a temporary additional ombudsman.

Mediation agreement — a formal document reflecting resolution of a contested FDA decision or action between FDA and a sponsor, applicant or manufacturer

Medical Devices Dispute Resolution Panel — the advisory Panel that functions under the charter of FDA's Medical Devices Advisory Committee, pursuant to §§ 514(b)(5), 515(g)(2)(B), 522(b), and 562 of the FD&C Act, to provide independent recommendations concerning scientific disputes between FDA and medical device sponsors, applicants, or manufacturers.

Requesting party - 1) a medical device sponsor, applicant, or manufacturer who has a scientific dispute with FDA and who requests a review of the matter by the Medical Devices Dispute Resolution Panel; or 2) FDA, when it exercises its discretion and refers a scientific dispute to this Panel for review.

Scientific dispute (or scientific controversy or issue) — a disagreement with an FDA science-based decision or action, which bears on a regulatory matter pending before FDA, or an appeal arising from an FDA science-based decision that served as the basis for a regulatory decision. This term *excludes* matters relating to potential criminal activity, allegations of intellectual or regulatory bias, FDA's designation of a lead Center to regulate a combination product, and legal issues.

Statement of Findings — a written administrative record of the case review findings and recommendations by the Medical Devices Dispute Resolution Panel, which is transmitted to the CDRH Director.

Writing — includes a submission by fax or email.

D. Composition of the Dispute Resolution Panel

1. Membership

Pursuant to the charter of the Medical Devices Advisory Committee, the Dispute Resolution Panel will have eight members.

Five standing members appointed to four-year terms, including a nonvoting member representing consumer interests and a nonvoting member representing industry interests. One of the standing members will be appointed by FDA to serve as the Chair.

Standing members will have general scientific expertise applicable to a broad range of scientific issues (*e.g.*, biostatistician, general internist or epidemiologist); and

Three temporary voting members appointed by FDA to participate in the review of a specific dispute. Temporary voting members will be selected based on their experience, expertise, or analytical skills relevant to the review of a particular disputed issue.

The temporary voting members will be drawn from —

(a) current members of other Panels of the Medical Devices Advisory Committee,
(b) current special Government employees serving as consultants to the Medical Devices Advisory Committee or other FDA advisory Panels or committees, and
(c) other sources such as persons nominated to fill vacancies on FDA Advisory Committees in response to Federal Register announcements; persons suggested by the Chair and members of the Dispute Resolution Panel and of other panels; suggestions from the parties regarding the kinds of expertise that are needed for a particular dispute; and other sources as may be determined by the CDRH Ombudsman.

Temporary voting members will not be drawn from a Medical Devices Advisory Committee Panel —

- that has had significant prior involvement with the particular issue in dispute; or

- where there is a reasonable expectation that it will be asked to render advice on essentially the same scientific dispute or application at a later date.

Notices requesting nominations for members of the Dispute Resolution Panel will be published in the *Federal Register* in accordance with 21 C.F.R. §§ 14.82 (for voting standing and temporary members) and 14.84 (for non-voting members). Because the Panel meeting may take place within a very short time (normally 60 days) of granting the request for the meeting, nominations for temporary members will usually not be solicited in the Federal Register each time the Panel is to review a dispute. In selecting all Panel members and consultants, FDA will emphasize expertise and diversity in relevant scientific and health professional education, qualifications, training, and experience.

As special Government employees, Dispute Resolution Panel members will be subject to all applicable conflict-of-interest laws and regulations. Prior to final selection of members, potential conflicts-of-interest will be carefully scrutinized. If and when such conflicts are identified, nominees may be disqualified. If a conflict of interest is discovered or arises after a candidate is selected and seated on the Dispute Resolution Panel, the member may be granted a waiver pursuant to Federal ethics rules, or be recused from the issue that may be affected by the member's conflict, or, if the conflict was deliberately concealed, may be dismissed from the Panel.

2. Term of Service

A standing member of the Dispute Resolution Panel will serve continuously for a single four-year term[6], unless extenuating circumstances allow or require a member to be excused, pursuant to 21 C.F.R. 14.80 (e) and (f). A temporary voting member will serve for an indefinite term, ending when the CDRH Director takes final action on the particular dispute for which that member had been selected to review as a Panel member.

[6] In order to provide for the orderly recruitment and replacement of the standing Panel members, the initial appointments to the Dispute Resolution Panel were staggered.

E. How To File A Request For Review Of A Scientific Dispute

1. Timeframe for making a request

A party may request review by the Dispute Resolution Panel by submitting a written request within the 30 days[7] following the decision or action he or she wants the Panel to review. If FDA had notified the party of the decision or action in writing,[8] the 30 days will begin running from the date the party received the writing. This 30-day limit may be waived if circumstances warrant, as long as an unreasonable amount of time has not elapsed since the decision or action occurred.

2. Mailing address

The request for Dispute Resolution Panel review and all subsequent correspondence should be addressed to:

CDRH Ombudsman
Office of the Center Director (HFZ-5)
Center for Devices and Radiological Health
U.S. Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

3. Content

A request for Dispute Resolution Panel review should contain the following:

(a) The name and mailing address of the medical device sponsor, applicant, or manufacturer who is the requesting party.

(b) The name, mailing address, e-mail address, and phone number of the person who will serve as the contact point for the requesting party.

[7] Unless otherwise stated all timeframes are in calendar days and include weekends and holidays.

(c) An explanation of why the requesting party believes it has standing to request review of the particular matter by the Dispute Resolution Panel.

(d) A concise summary of the scientific issue in dispute, including a summary of the particular FDA action or decision to which the requesting party objects, any prior advisory Panel action, and the results of any efforts that have been made to resolve the dispute.

(e) A clear summary of the arguments and relevant data and information. Material outside the official administrative record and not in the possession of FDA at the time the decision or action in dispute was made may be submitted only if it is a new interpretation of data or information already in that record.

(f) A clear statement of the action requested of FDA.

4. Acknowledgment

The CDRH Ombudsman will provide a written acknowledgment to the requesting party, normally within five working days of receiving a written request for review.

5. Effect of filing a request for review by the Dispute Resolution Panel

The filing of a request for, or FDA's granting of, a review of a matter by the Dispute Resolution Panel will not affect, delay, stay, or preclude any ongoing or future seizure, recall, suspension of marketing authority, or other regulatory action that FDA deems necessary to protect the public health.

6. FDA-initiated Referrals

FDA may at any time exercise discretion and initiate a referral of a scientific dispute to the Dispute Resolution Panel for review, even when the other party (a sponsor, applicant or manufacturer) has not made such a request, providing the following conditions are met:

(a) The scientific dispute involves FDA and a medical device sponsor, applicant, or manufacturer whose interests are or are likely to be adversely affected by an FDA decision or action.

(b) Reasonable efforts have been made by FDA to resolve the dispute through established processes, if appropriate, including review by the Center's supervisory chain of command (see 21 C.F.R. § 10.75), and there is reason to believe that further supervisory review will not resolve the matter.

(c) The referral is consistent with the Eligibility Review criteria. (See item 8 below).

A referral by FDA is subject to the same requirements for public notice and notification of affected parties as a request from any other source.

7. Inquiries Concerning the Process

Inquiries concerning how to obtain Dispute Resolution Panel review should be directed to the CDRH Ombudsman by e-mail (ombudsman@cdrh.fda.gov), by calling 301-443-6220 x119, or by fax to 301-827-2565. General information about the Dispute Resolution Panel, its procedures, and how to obtain review of disputed matters will be provided and regularly updated on the CDRH web site (at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html).

8. Eligibility Review

Upon receipt of a complete request for Dispute Resolution Panel review, the CDRH Ombudsman, in consultation with the Panel Chair, will determine whether the dispute is eligible for review. To be eligible for Dispute Resolution Panel review, the following criteria should be met:

(a) the request primarily concerns a scientific controversy that meets the definition of this term in Section C. above;

(b) the request demonstrates sound scientific grounds supporting reconsideration of information, data, evidence or views contained in the administrative record;

(c) the dispute is at an appropriate stage (which will vary from case to case) for Dispute Resolution Panel review, and the requestor has made sufficient effort to resolve the dispute through less formal dispute resolution mechanisms, particularly review up the supervisory chain as provided by 21 C.F.R. § 10.75. FDA's goal is to resolve disputes fairly and expeditiously. In some cases, this might mean skipping or collapsing some steps in an appeal mechanism like the supervisory chain. However, FDA believes that internal review up the supervisory chain is a reasonable approach in most cases because it is likely to help clarify the issue in dispute, to ensure that additional FDA perspectives and experience are brought to bear on a dispute, and to create the record for a subsequent meaningful review by the Panel, if needed.

Most appeals the Panel will hear will be for devices that are well along in their development, when the sponsor believes it has submitted sufficient data to establish that the device should be marketed, but FDA has disagreed and issued a non-approvable letter for a premarket approval application (PMA) or a not substantially equivalent determination for a premarket notification (510(k)).

It may also be appropriate for the Panel to review a dispute that arises earlier in the device development and approval process, for example, about the reasonableness of safety and efficacy data that FDA requires for a particular product or product type or technology. FDA believes the vast majority of these "early" disagreements, including those regarding the results of determination and agreement meetings under § 205 of FDAMA (§ 513(a)(3) of the FD&C Act), should be resolved by involving the supervisory chain pursuant to 21 C.F.R. § 10.75 because that is likely to be the quickest and least resource intensive approach for FDA and the sponsor. Moreover, Panel review may not be appropriate at early stages in the process for a variety of reasons:

If there has been only a preliminary CDRH decision or action, there may not be an actual controversy; the controversy may not be sufficiently well-defined for Panel review to be possible or useful; or a disagreement may not be sufficiently significant to justify the resources required by a Panel review. In addition, if the Panel is faced with a high volume of disputes, the usefulness of the Panel could be compromised by backlogs and difficulties in convening frequent meetings, which would prevent timely reviews and rapid resolution of appropriate disputes. However, FDA does not intend to make any particular type of appeal a prerequisite for requesting review by the Dispute Resolution Panel.

It is important to remember that persons with disputes that are not reviewed by the Dispute Resolution Panel will still have a wide range of effective dispute resolution mechanisms available to them. These mechanisms are described in CDRH's February 1998 guidance document, *MEDICAL DEVICE APPEALS AND COMPLAINTS - Guidance on Dispute Resolution*. In addition, the CDRH Ombudsman is available to facilitate the resolution of disputes at any time, even early in the product review process.

(d) the request has been submitted within 30 days of a disputed FDA action or decision, though FDA may accept a request after 30 days as long as an unreasonable amount of time has not elapsed;

(e) the request is submitted by 1) a party with standing to bring the issue before the Dispute Resolution Panel, *i.e.*, a medical device sponsor, applicant, or manufacturer; or 2) FDA, on its own initiative, and the other party is a sponsor, applicant or manufacturer whose interests are or are likely to be adversely affected by an FDA decision or action;

(f) the FD&C Act and FDA regulations do not require use of a different method of review or appeal;

(g) the dispute does not involve:

(1) actual or potential criminal activity (*e.g.*, data fraud, submission of false information, FDA employee misconduct, unauthorized disclosure of proprietary information);
(2) allegations of intellectual or regulatory bias (including differential treatment) on the part of FDA employees, members of FDA advisory panels, or other special Government employees;
(3) regulatory jurisdiction (*i.e.*, which FDA component will have lead regulatory responsibility for a particular matter) or other matters in which regulatory policy or procedures are the dominant concerns;
(4) a legal issue; or
(5) a matter for which the CDRH Director has not been delegated authority;

(h) the matter in dispute is sufficiently complex that specialized expertise and independent review by the Dispute Resolution Panel is warranted; and

(i) reconsideration of FDA's decision or action is not outweighed by public health or other considerations.

CDRH will weigh the need for Panel review against such considerations as efficiency, timeliness, economy, and Panel and staff resources available for all disputes.

In determining whether there should be Panel review, the Ombudsman will strive to ensure that the interests of fairness and objectivity are served. However, this could sometimes result in a rejection of a request for Panel review. For example, if the CDRH Director had made, or substantially participated in, the decision or action for which a party is requesting Panel review, FDA might deny the request for review. Because the Panel makes a recommendation to the CDRH Director, the fairness of the process in general and the objectivity of the CDRH Director in particular could be called into question if he or she had to decide to accept a Panel recommendation to overrule the Director's own decision. (In some instances, where it appears a particular dispute may ultimately be the subject of a request for Panel review, a CDRH Deputy Director, instead of the CDRH Director, may make or

substantially participate in a Center decision or action. In these cases, if the Panel subsequently reviews the dispute, the CDRH Director could accept or reject the Panel's recommendations).

Various scenarios illustrating how FDA expects to grant or deny requests for Panel review of scientific disputes are provided in Appendix A.

Upon completion of the eligibility review, the CDRH Ombudsman will take one of the following actions:

(1) Notify all parties that the request for review has been granted and, if appropriate, offer mediation as an alternative to Panel review.
(2) Notify all parties that the request for review has been denied and provide an explanation of the reasons for denial. The Ombudsman also will provide information on alternative dispute resolution (including mediation, if appropriate) and any other appeal processes that may be available to the requestor.
(3) If the request was incomplete, the Ombudsman may request additional information necessary to make a determination.

The Ombudsman will normally make a decision within 15 days of receipt of the request unless circumstances require a longer review period. Where circumstances require more than 15 days to make a decision, the Ombudsman will provide a written notice to the requesting party, and will include an estimate of when a decision should be expected.

9. Consultation Prior to Denial of a Request

If the CDRH Ombudsman believes that a request for review has not met the eligibility criteria, or based on other considerations, the request should not be granted, the Ombudsman will consult with the appropriate Deputy Center Director before making a final determination concerning the request. The Ombudsman will deny a request for Dispute Resolution Panel review only if the Deputy Center Director concurs with the denial.

10. Scheduling of the Panel Meeting

Upon granting a request for Panel review, the CDRH Ombudsman will:

(a) schedule a Panel meeting at such time as will ensure a full and timely hearing of the issues involved; normally, this will be within 60 days of FDA's granting the request, but could be longer if needed to identify, select, and appoint the three temporary Panel members; to accommodate the schedules and workloads of the parties, the Panel members, and the Ombudsman; and to complete various administrative and logistical tasks related to the meeting;

(b) at least 15 days prior to a Panel meeting, as specified in 21 C.F.R. § 14.20, publish a *Federal Register* notice announcing the date, time, and location of the meeting and, to the extent consistent with protection of non-public information, the topics to be discussed; and

(c) after the parties submit views to the CDRH Ombudsman, prepare a review package that includes a written summary of the matter in dispute, along with the arguments, relevant data and information submitted by the parties, for distribution to the parties and Panel members no later than 15 days prior to the Panel meeting.

11. Denial of a Request

If the Center decides to deny a request for Dispute Resolution Panel review, the CDRH Ombudsman will, in writing, inform the requesting party of the reasons for the denial. The Ombudsman also will inform the requesting party of alternative avenues for obtaining reconsideration of the disputed matter, including an appeal of the denial to the FDA Ombudsman in the Office of the Senior Associate Commissioner. If the Center denies a request for Dispute Resolution Panel review, the sponsor, applicant, or manufacturer may still be able to use other appropriate means of resolving the dispute; see FDA's guidance, *Medical Device Appeals and Complaints — Guidance on Dispute Resolutions* (February 1998) for information on these alternatives. (This guidance is available on FDA's web site at www.fda.gov/cdrh/modact/dispresl.pdf).

F. Panel Meeting Procedures

All meetings of the Dispute Resolution Panel will be governed by FDA regulations at 21 C.F.R. Part 14. Panel meetings will normally follow the following procedures:

- All Panel meetings will be open to the public as provided by the Federal Advisory Committee Act and FDA regulations unless a portion of a meeting is closed pursuant to 21 C.F.R. § 14.27.

- The sponsor, applicant or manufacturer will speak first (even if FDA is the requesting party) and present its views, after which FDA representatives and other affected and interested persons may address the Panel.

- Each party (the sponsor, applicant or manufacturer on the one hand and FDA on the other) may be accompanied by scientific experts, health professionals, legal counsel, and other technical specialists for the purpose of providing supplementary testimony or responding to questions by members of the Dispute Resolution Panel, pursuant to 21 C.F.R. § 14.29.

- During and after the presentations by both parties, members of the Dispute Resolution Panel may question the parties directly. No questioning by or debate between the parties will be permitted.

- Every Panel meeting will offer at least a one hour open public hearing during which the Panel may hear, to the extent practicable, arguments and receive information relevant to the proceeding from the general public.

- Once deliberations have been completed, the Chair will determine if a consensus exists among Panel members and, if not, will call for a vote. The Chair will not vote, except that, in the case of a tie vote, the Chair will cast the deciding vote.

- FDA will provide for the transcription of all Panel meetings, and copies of transcripts will be available to the public pursuant to 21 C.F.R. 14.61; the Freedom of Information Act, 5 U.S.C. § 552; and FDA's Public Information regulations, 21 C.F.R. Part 20.

Within 15 days of the Dispute Resolution Panel meeting, the CDRH Ombudsman will prepare a written Statement of Findings summarizing the Dispute Resolution Panel findings and recommendation, including any minority views. The Ombudsman will provide a copy of the Statement of Findings in draft form to the Panel Chair and to each Dispute Resolution Panel member who participated in the proceeding for review; Panel members will then have 10 days to provide any comments to the Ombudsman. Within five working days, the Ombudsman will consult with the Panel Chair and prepare a final Statement of Findings, making such changes as are necessary to accurately reflect the Panel's review and recommendation. The Panel Chair will sign the final Statement of Findings within five working days of receiving it, and will forward it to the CDRH Director.

G. FDA Action on Panel Findings and Notification of Decision

Within 10 days of receiving both the Statement of Findings and the transcript of the Panel meeting, the CDRH Director will take one of the following actions:

(a) Concur with the Panel recommendation(s);
(b) Concur with the Panel recommendation(s) with specified exception(s);
(c) Not concur with the Panel recommendation(s) and direct that specified action(s) be taken (e.g., determine that additional information, evidence or deliberation is necessary and remand the matter to the Dispute Resolution Panel, or to another Panel of the Medical Devices Advisory Committee, with instructions for further consideration); or conclude that the matter was not an appropriate matter for review by the Dispute Resolution Panel and that a separate investigation is required, and refer the matter to an appropriate FDA or other governmental investigative unit.

Following a conclusion by the CDRH Director regarding the scientific dispute, the CDRH Ombudsman will, in writing, notify the sponsor, applicant or manufacturer, its authorized representatives, and appropriate FDA officials of the decision by the CDRH Director, required action resulting from the decision, if any, and any rights of appeal that exist should the parties disagree with the decision.

The Statement of Findings and the decision of the CDRH Director will be made part of the official administrative record.

H. Appeal of CDRH Director's Decision or Action Following Dispute Resolution Panel Review

(1) A decision or action by the CDRH Director following a Dispute Resolution Panel review is not a final FDA action for purposes of judicial review unless otherwise provided by statute or regulation.

(2) A decision or action by the CDRH Director following a Dispute Resolution Panel review may be appealed in writing to the FDA Ombudsman (not the CDRH Ombudsman) in the Office of the Senior Associate Commissioner. The FDA Ombudsman will not make an independent determination of whether or not to overrule the CDRH Director, but will work informally with the Center and the party appealing such decision or action to develop a mutually acceptable approach. The FDA Ombudsman may be contacted at:

Office of the Ombudsman
Office of the Senior Associate Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Room 14B-03, HF-7
Rockville, MD 20857

Telephone: 301-827-3390
Facsimile: 301-480-8039
E-mail: ombudsma@oc.fda.gov (note: "ombudsma" is *not* a typo)

(3) Any party who wishes to appeal a CDRH decision or action following a Dispute Resolution Panel proceeding on the basis of an alleged conflict-of-interest involving a Dispute Resolution Panel member should contact the CDRH Advisory Panel Coordinator who, if warranted, will refer the matter to the appropriate FDA component for review and possible investigation.

I. Public Availability of Dispute Resolution Panel Records

As a matter of general practice, FDA will make publicly available all materials collected, prepared and presented to the Dispute Resolution Panel at the time of the Panel meeting, as provided by 21 C.F.R. § 14.65 (c).

Following a meeting of the Dispute Resolution Panel, requests for materials, including a Statement of Findings and a written decision by the CDRH Director, must be made through the Freedom of Information Act process (see 21 C.F.R. Part 20).

J. Mediation

At the time FDA grants a request for Dispute Resolution Panel review, it may also make an offer of mediation as an alternative to Panel review. FDA may also make an offer of mediation when it denies a request for Dispute Resolution Panel review. An offer of mediation will define the scope of the proposed mediation. If FDA offers mediation, the requesting party has 15 days from the date of the notification to accept or reject the offer. Any acceptance must be in writing. Failure to accept an offer of mediation within 15 days may be considered a rejection of the offer.

If the requesting party accepts an offer for mediation, the CDRH Ombudsman or his designee (e.g., another FDA employee trained in mediation, a mediator under contract to FDA, etc.), in the role of a neutral facilitator, will initiate the mediation sessions with the parties as soon as practicable. Mediation should generally be completed within 90 days.

The mediator will periodically inform the appropriate Deputy Center Director of the progress of ongoing mediation efforts. CDRH representatives engaged in mediation as the FDA party may periodically consult with the Deputy Center Director for the purpose of obtaining the Deputy Center Director's views and guidance.

If the parties reach agreement, the CDRH Ombudsman will document the outcome in a Mediation Agreement that reflects the resolution of the scientific dispute. Copies of the Agreement will be provided to all parties involved in the mediation, and will become part of FDA's files.

In accordance with sections 571(5) and 574 of the Administrative Dispute Resolution Act of 1990, as amended by the Alternative Dispute Resolution Act of 1996, P.L. 104-320, 5 U.S.C. §§ 571(5) and 574, all records of communications prepared for the purpose of mediation, including any memoranda, notes, or work products, excluding the Mediation Agreement, will be confidential.

If, in the judgment of the mediator, mediation efforts have failed to achieve satisfactory progress within a reasonable time, the mediator may, upon written notice to the parties, terminate mediation. Also, either party may terminate mediation at any time.

Once mediation is terminated, if FDA had previously granted a request for a review by the Dispute Resolution Panel, that review will then proceed following the usual procedures and schedule; if FDA had previously denied such a request, referral to the Panel may be reconsidered.

K. Timeline of a Review by the Dispute Resolution Panel

Filing a request for review — A complete request for review by the Dispute Resolution Panel should be filed within 30 days of the time the FDA action or decision was issued for which the review is sought. FDA may accept a request after 30 days as long as an unreasonable amount of time has not elapsed.

FDA acknowledgment — The CDRH Ombudsman will provide written acknowledgment of a request for review within five working days of receipt.

Eligibility review — The CDRH Ombudsman will complete the eligibility review within 15 days unless circumstances require more than 15 days.

Response to an offer of mediation — If FDA makes an offer of mediation, it must be accepted within 15 days or FDA may consider the offer rejected.

Mediation — Mediation should generally be completed within 90 days.

Dispute Resolution Panel meeting — FDA will attempt to schedule a Dispute Resolution Panel meeting within 60 days of a decision to grant a request for Panel review. FDA will publish a *Federal Register* Notice announcing the meeting at least 15 days prior to the meeting and will provide a review package of the matter in dispute to the parties and Panel members at least 15 days prior to the meeting.

Preparation of a Statement of Findings — The CDRH Ombudsman will prepare a draft Statement of Findings summarizing the findings and recommendations of the Dispute Resolution Panel within 15 days of the Panel meeting. The Panel Chair and members will have 10 days to provide any comments to the Ombudsman. The Ombudsman will consult with the Panel Chair and will prepare a final Statement within 5 working days of receiving comments. The Panel Chair will approve the final Statement of Findings within 5 working days of receiving it.

CDRH Director Decision — The CDRH Director will normally make a decision within 10 days of receiving both the Panel's Statement of Findings and the transcript of the Panel meeting

(All timeframes are based on calendar days unless otherwise noted).

L. Additional Sources of Information

1. Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 *et seq*.)
2. Federal Advisory Committee Act (5 U.S.C. App. II).
3. Administrative Dispute Resolution Act of 1996 (5 U.S.C. 571-584).
4. 21 C.F.R. Part 14 — Public Hearing Before A Public Advisory Committee.
5. Medical Device Appeals and Complaints — A Handbook On Dispute Resolution.
6. Policy & Guidance — Handbook For FDA Advisory Committees.

APPENDIX A

Medical Devices Dispute Resolution Panel Review Request Scenarios

The following hypothetical cases illustrate how FDA expects to decide whether to grant a request for review of a scientific dispute by the Medical Devices Dispute Resolution Panel.

I. Cases That May be Eligible for Dispute Resolution Panel Review

Scenario 1:

CDRH finds a particular 510(k) submission is "not substantially equivalent" (NSE) to the predicate product for scientific reasons. The applicant is unsuccessful in persuading ODE line management that the NSE decision is based on a misinterpretation of the underlying science by ODE review staff and requests review by the Dispute Resolution Panel.

Scenario 2:

The Orthopedic and Rehabilitation Devices Panel recommends against approval of a bone implant PMA. The Center concurs with the recommendation and issues a disapproval. The applicant lodges a protest against FDA's decision, alleging that: (1) the Panel and FDA erred in concluding that reasonable evidence of safety and effectiveness had not been presented; and (2) the Panel and FDA selectively considered the scientific information. The applicant requests independent review of the entire data set by the Dispute Resolution Panel.

Scenario 3:

A device company enters into a PDP with CDRH to prevent any misunderstanding with respect to the type and amount of clinical data needed to support a marketing application. Following completion of the studies, the applicant submits its data and is told that the data submitted do not meet the terms of the PDP. Efforts by the firm to appeal this judgment through the ODE management chain are unsuccessful. A request is made to have the Dispute Resolution Panel review the matter.

Scenario 4:

An ODE review division notifies an applicant that a PMA is "not fileable" because of incomplete scientific data. ODE management affirms this view. The applicant holds a differing view and requests that the Dispute Resolution Panel decide who is right.

Scenario 5:

An order to require a five-year post-market surveillance study is issued by FDA. The affected company believes that such a study is not necessary, stating that no scientific purpose is served by collecting data beyond a three-year period. The company asks for review of the matter by the Dispute Resolution Panel.

Scenario 6:

With active involvement by the Center, FDA issues a Warning Letter indicating the possibility of enforcement action against a manufacturer if it continues to market a product as originally labeled despite the availability of new scientific information indicating the potential for a serious, previously unforeseen health hazard. Despite requests by the manufacturer to stay the enforcement action due to a difference of opinion over the science, FDA stands firm. The manufacturer requests Dispute Resolution Panel review. *Note:* Although Dispute Resolution Panel review may be granted, the filing of a request for review by the Dispute Resolution Panel will not affect, delay, stay, or preclude any ongoing or future seizure, recall, suspension of marketing authority, or other regulatory action which FDA deems necessary to protect the public health. See Section E. (5) "Effect of filing a request for review by the Dispute Resolution Panel."

Scenario 7:

A PMA applicant is told by the lead CDRH reviewer that an additional clinical study is needed in order to fully evaluate the submission. The applicant contests the additional information request on the grounds that it constitutes scientific excess and differential treatment compared to the data requirements imposed on competitors. The applicant requests Dispute Resolution Panel review. (Although appeal up the supervisory chain should probably be pursued as a matter of first course, it will not be a prerequisite for Panel review in all cases.)

Scenario 8:

An IDE applicant requests and obtains a pre-submission conference with ODE division staff and a subsequent meeting with Office-level officials in an effort to reach agreement over the PMA data requirements for a particular investigational device. The two sides find they are worlds apart, leaving the applicant to believe that an impartial review of the matter is the only means by which to settle the disagreement.

II. Cases that May Not be Eligible for Dispute Resolution Panel Review

Scenario 1:

A "for cause" inspection of a device manufacturer is conducted by FDA bioresearch monitoring investigators as a result of information provided by a competitor firm. The inspection turns up evidence of possible data fraud associated with an approved market application. The manufacturer wishes to defend the integrity of the data through independent review and validation, and asks for review of the matter by the Dispute Resolution Panel.

Primary reason why Panel review may not be granted: Request relates to an allegation of criminal misconduct, a matter that is outside the purview of the Dispute Resolution Panel.

Scenario 2:

A company is informed by an FDA district office that it is unlawfully marketing a medical device and that distribution should be halted pending submission to and clearance by FDA of a 510(k). The firm challenges the decision and asserts that the product does not meet the legal definition of a medical device. In support of its requirement, the firm cites a variety of publications, which FDA finds unpersuasive. Efforts by the CDRH Ombudsman to mediate the dispute are unsuccessful, leading the firm to request a review by the Dispute Resolution Panel.

Primary reason why Panel review may not be granted: The issue is not a scientific issue; it involves a question of regulatory jurisdiction requiring a legal/regulatory determination that is outside the scope of the Dispute Resolution Panel.

Scenario 3:

A company seeking to market a drug-device combination product is told by FDA that the product must be regulated as a drug. The company disagrees and submits scientific evidence purporting to show that the device component is the primary mechanism of action. After a review of the scientific evidence proffered by the firm, FDA reaffirmed its requirement. The manufacturer asks for an independent review of the evidence by the Dispute Resolution Panel.

Primary reason why Panel review may not be granted: The FDA Ombudsman in the Office of the Senior Associate Commissioner has exclusive authority to resolve product jurisdiction issues. This is outside the purview of the Dispute Resolution Panel.

Scenario 4:

A competitor of a PMA holder challenges the scientific basis of FDA's approval, claiming that new, post-approval information has come to light calling the approval into question and implying new safety concerns. The competitor asks for independent review by the Panel.

Primary reason why Panel review may not be granted: Only the "sponsor, applicant, or manufacturer" can request a review of a matter by the Dispute Resolution Panel. The competitor does not have standing and must use one of the alternative dispute resolution processes provided by the FD&C Act or FDA regulations.

APPENDIX B

Sample Statement of Findings Memorandum

MEMORANDUM

Date:

To: CDRH DIRECTOR

From: Medical Devices Dispute Resolution Panel

Subject: Medical Devices Dispute Resolution Panel Statement of Findings
[Identify case by name of party.]

ISSUE

(Provide a concise summary of the FDA decision/action being disputed, the effective date of the decision/action being disputed if applicable, the identity of the party or parties contesting the decision/action, the date of review by the Medical Devices Dispute Resolution Panel, and a brief overview of the Panel findings.)

PRELIMINARY ACTIONS

(Describe all pre-Panel efforts to resolve the dispute, including supervisory re-consideration, formal petitions for re-consideration, mediation by the CDRH Ombudsman, etc. Also provide the date the request for Panel review underwent preliminary review by the CDRH Ombudsman and Dispute Resolution Panel Chair, the reasons for proceeding with Dispute Resolution Panel review of the matter, and the composition of the Panel that reviewed the matter, including any waivers that may have been granted to individual Panel members.)

KEY FACTS CONSIDERED

(Give a synopsis of the arguments, written and oral, and substantiating data and information presented by the requesting party or authorized representative, in addition to any such information offered by other interested and affected parties, prior to and during the meeting of the Dispute Resolution Panel. Information outside the administrative record should be highlighted and the basis [e.g., new interpretation of data] for permitting its consideration This section should also include relevant citations from the FD&C Act, FDA regulations and FDA policies that bear on the original CDRH decision/action and the subsequent dispute. Also provide any public health impacts asserted by the disputing parties in relation to the contested decision/action or that purportedly could result if the decision/action is either upheld or reversed.)

Sample Statement of Findings Memorandum (Continued)

STATEMENT OF FINDINGS AND RECOMMENDATION

(Provide an overview of the Panel's deliberations, including areas of agreement and disagreement among the members, key concerns, the Panel's overall conclusions and recommendations, and the final vote if one was taken. Include minority views.)

CONCURRENCE

The Medical Devices Dispute Resolution Panel met on (insert date) for the purpose of reviewing (restate the name of the case and case number). The Panel has reviewed and endorses this Statement of Findings and Recommendations.

_____

Panel Chair Date

CENTER DIRECTOR DECISION

[ ] I concur with the Panel recommendation(s).

[ ] I concur with the Panel recommendation(s) with the following exception(s):

[ ] I do not concur with the Panel recommendation(s) and direct that the following action(s) be taken:

_____

David W. Feigal, Jr., M.D., M.P.H. Date
Director, Center for Devices and Radiological Health
U.S. Food and Drug Administration

APPENDIX C

Extracts from the Food, Drug, and Cosmetic Act

21 U.S.C. § 351 *et seq.*

These extracts highlight the statutory role and responsibilities assigned by FDA to the Medical Devices Dispute Resolution Panel. The official version, as provided by Title 21 of the United States Code, should be consulted for the full text of these provisions.

§ 514(b)(5) — Performance Standards — Report and recommendation by advisory committee.

(A) The Secretary —

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments ...,

to an advisory committee of experts ... for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. .... The advisory committee shall, within sixty days of the referral ... submit ... a report and recommendation respecting such regulation .... A copy of such report shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be Panels under section 513) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this Act. Each such committee shall include as non-voting members a representative of consumer interests and a representative of interests of the device manufacturing industry. ....

§ 515(g) — Premarket Approval (PMA and PDP) — Review.

(1) Upon petition for review of —

> (A) an order ... approving or denying approval of an application or an order ... withdrawing approval of an application, or
> (B) an order ... revoking an approved protocol, ... declaring that an approved protocol has not been completed, or ... revoking the approval of a device,

the Secretary shall, unless he finds the petition to be without good cause or unless a petition for review ... has been submitted under paragraph (2), hold a hearing ... on the order. .... Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, approving or denying approval of the application, reinstating the application's approval, approving the protocol, or placing in effect a notice of completion.

(2) —

> (A) Upon petition for review of —
>
> > (i) an order ... approving or denying approval of an application or an order ... withdrawing approval of an application, or
> > (ii) an order ... revoking an approved protocol, ... declaring that an approved protocol has not been completed, or ... revoking the approval of a device,
>
> the Secretary shall refer the application or protocol subject to the order and the basis for the order to an advisory committee of experts established pursuant to subparagraph (B) for a report and recommendation with respect to the order. The advisory committee shall, after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation, together with all underlying data and information and a statement of the reasons or basis for the recommendation. A copy of such report shall be promptly supplied by the Secretary to any person who petitioned for such referral to the advisory committee.
>
> (B) The Secretary shall establish advisory committees (which may not be Panels under section 360c of this title [§ 513 of the FD&C Act]) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional backgrounds, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. .... The Secretary shall designate the chairman of an advisory committee from its members. The Secretary ... shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(C) The Secretary shall make public the report and recommendation made by an advisory committee ... and shall by order, stating the reasons therefore, either affirm the order referred to the advisory committee or reverse such order and, if appropriate, approve or deny approval of the application, reinstate the application's approval, approve the protocol, or place in effect a notice of completion.

§ 522(b) — Postmarket Surveillance — Surveillance Approval. (This provision was added by § 212 of the Food and Drug Administration Modernization Act of 1997.)

Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required ... to conduct such surveillance, submit ... a plan for the required surveillance. .... The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination ... that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.

§ 562 — Dispute Resolution. (This provision was added by § 404 of the Food and Drug Administration Modernization Act of 1997.)

If, regarding an obligation concerning ... devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate ... advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.