

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0239]

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Medical Devices; Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices." The guidance describes the role and operation of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee (the Dispute Resolution Panel), the types of controversies eligible for review by the Dispute Resolution Panel, and recommendations for submitting a request for review.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Resolving Scientific Disputes Concerning the Regulation of Medical Devices" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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FOR FURTHER INFORMATION CONTACT: Les S. Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-6220, ext. 119.

SUPPLEMENTARY INFORMATION:

I. Background

Section 404 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 (section 562 of the Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb-1)) requires FDA to establish procedures for the review of scientific controversies where there is not already an existing right of review. Although FDA believes existing procedures, such as internal agency review of decisions under § 10.75 (21 CFR 10.75), provide for an appropriate review of most, if not all, disputes, the Center for Devices and Radiological Health (CDRH) is developing new procedures to ensure effective and timely review of scientific disputes. In fact, CDRH has recently taken significant steps to achieve this objective, including the appointment of its first CDRH Ombudsman and the establishment of an advisory Dispute Resolution Panel. CDRH is now announcing a final guidance document on the use of this new Dispute Resolution Panel to facilitate the fair and rapid resolution of scientific disputes.

This guidance supersedes the April 27, 1999 (64 FR 22617), draft guidance document entitled “Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel.”

The Dispute Resolution Panel, chartered on August 18, 1999, has five standing members (including a nonvoting industry representative and a nonvoting consumer representative), and three additional temporary voting members appointed for each particular dispute. Standing members will have broad, crosscutting scientific, clinical, analytical, or mediation skills. Temporary members will be chosen based on their experience, expertise, or analytical skills relevant to the review of

each particular dispute. FDA published a notice in the **Federal Register** of November 10, 1999 (64 FR 61352), requesting nominations for the Dispute Resolution Panel members. The five standing members have since been appointed, and the first meeting of the Dispute Resolution Panel, an open public session, was held on October 31, 2000; the Dispute Resolution Panel members heard presentations from FDA and the device industry on the role of this panel in dispute resolution.

A. Response to Comments on the Draft Guidance

Three comments were submitted concerning the April 27, 1999, draft guidance, two from medical device industry associations—Health Industry Manufacturers Association (now AdvaMed) and the Medical Device Manufacturers Association, and one from a device firm. CDRH’s response to the significant comments follows:

Why a guidance document and not a regulation?

Two comments stated that FDA should issue a regulation instead of a guidance document to establish procedures to resolve scientific disputes.

FDA believes that it is not required to issue a regulation concerning the Dispute Resolution Panel procedures. The relevant section of FDAMA required a regulation only in those cases where no other statutory provision or a codified regulation provided a right of review of the matter in controversy. At the time of FDAMA’s enactment, FDA already had a wide range of dispute resolution mechanisms in place, including § 10.75, “Internal agency review of decisions.” That regulation permits any interested person to obtain review of any FDA decision. To implement the dispute resolution section of FDAMA, FDA amended § 10.75 to make it clear that a scientific controversy may be brought before an advisory panel or committee in appropriate circumstances. The agency concluded that a new regulation was not required. However, each center prepared guidance setting forth procedures tailored to meet the needs of persons affected by the different processes used by each center. CDRH published a general guidance on dispute resolution within the center, “Medical Device Appeals and Complaints” (February, 1998), chartered and staffed the

Dispute Resolution Panel in 2000, and is issuing this guidance to facilitate use of that Panel. Furthermore, FDA believes it is important to develop experience under the final guidance before considering whether it might be useful, even though not required, to issue a regulation at some point in the future. The guidance permits both CDRH and industry greater flexibility in resolving a particular controversy than a regulation would.

B. Independence of the Process

One comment argued that the Dispute Resolution Panel should have final authority to reverse FDA decisions rather than just make recommendations to the CDRH Director. Another comment believed a Dispute Resolution Panel recommendation to the CDRH Director should stand unless the decision would be unlawful or pose a significant threat to public health.

The legislative history indicates that the purpose of section 562 of the act is “to assure that the regulated industry receives a fair and impartial hearing and that the FDA *receives sound recommendations and advice*” (H. Rept. 105–310 at 373 (October 7, 1997)) (emphasis added). Congress intends and expects any panel that reviews disputes will provide “recommendations and advice,” and that FDA must retain the final decisionmaking responsibility. The Dispute Resolution Panel will provide an important independent source of additional analysis and additional views that FDA will then use in making a final decision.

Two comments focused on the independence of the process related to the role of CDRH officials in deciding whether a request for Dispute Resolution Panel review would be granted or denied.

FDA is responding to these comments by strengthening the independence of the CDRH Ombudsman in that process. The Ombudsman will have authority to grant requests for Dispute Resolution Panel reviews, in consultation with the panel chair, without obtaining the approval of the Center Director, a Deputy Center Director, or anyone else in CDRH, although he would not be precluded from discussing the request with them to get background information about the dispute that would be helpful in making the decision to grant or deny review. However, if the Ombudsman

wishes to deny a request for Dispute Resolution Panel review, the Ombudsman will consult with, and obtain the concurrence of, the appropriate Deputy Center Director.

C. Thresholds for Review of Scientific Disputes

Two comments objected to statements in the draft guidance to the effect that a request for Dispute Resolution Panel review must primarily concern a scientific controversy regarding an FDA “decision or action.” The comments prefer an approach that would permit disagreements to be brought to the Dispute Resolution Panel “early” in the product review process, such as disagreements about the reasonableness of FDA data requirements, before there was an actual decision or action by the agency.

FDA agrees that there may be some early disputes that would be appropriate for, and could benefit from, a review by the Dispute Resolution Panel and has revised the guidance to include such examples.

D. Timeliness of the Process

Several comments were concerned that the process described in the draft guidance will not ensure timely review of disputes.

FDA has revised the guidance to streamline the process and tighten some of the timeframes for processing and reviewing disputes. In most cases, CDRH expects matters accepted for Dispute Resolution Panel review to receive a final decision within 90 to 120 days of receipt of the request. Practical and administrative constraints preclude developing a timeframe shorter than this.

II. Significance of Guidance

This guidance document represents the agency’s current thinking on the Dispute Resolution Panel procedures for resolving scientific disputes. 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 applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000.) This guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

As the agency gains experience with the Dispute Resolution Panel process, this guidance document may be revised from time to time.

III. Electronic Access

In order to receive "Resolving Scientific Disputes Concerning The Regulation Of Medical Devices" 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.

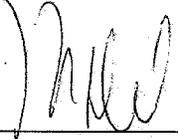
Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Paperwork Reduction Act of 1995

The information collection provisions contained in this guidance have been approved by the Office of Management and Budget (OMB) under OMB control number 0910-0467.

found in brackets in the heading of this document. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 6/15/01
June 15, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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