Dated: April 20, 1999.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0239]

Draft Guidance on Resolving Scientific Disputes Concerning the Regulation of Medical Devices; Administrative Procedures on Use of the Medical Devices Dispute Resolution Panel; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel.'' Section 404 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) directed FDA to ensure that it has effective processes to resolve the scientific disputes that occasionally arise between FDA and the regulated industry, including a review by an appropriate panel of experts to advise the agency on issues upon which industry and FDA professionals differ. This guidance is neither final nor is it in effect at this time.

DATES: Written comments concerning this guidance must be received by July 26, 1999. Written comments concerning the information collection requirements must be received by June 28, 1999.

ADDRESSES: Written comments concerning this guidance must be submitted 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. Submit written requests for single copies on a ''3.5'' diskette of the draft guidance document entitled ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical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'' 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 adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: James G. Norman, Center for Devices and Radiological Health (HFZ–2), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–4690.

SUPPLEMENTARY INFORMATION:

I. Background

FDA provides various mechanisms by which the device industry can obtain reconsideration of FDA decisions and actions under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), the Administrative Procedure Act (5 U.S.C. 551 *et seq.*), and agency regulations. These processes are summarized in a guidance document entitled ''Medical Device Appeals and Complaints Guidance on Dispute Resolutions,'' which is available from the CDRH web site at ''http://www.fda.gov/cdrh/resolvingdisputes''.

Section 404 of FDAMA added to these various mechanisms by directing 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. In the **Federal Register** of June 16, 1998 (63 FR 32733 and 32772), FDA published a direct final rule and a companion proposed rule amending § 10.75 (21 CFR 10.75) to add another method of resolving scientific controversies. This amendment stated that sponsors, applicants, or manufacturers of drugs (including human drugs, animal drugs, and human biologics), or devices may request review of scientific controversies by an appropriate scientific advisory panel or advisory committee. (Hereafter in this document, the term advisory committee includes scientific advisory panels.) By this amendment, FDA clarified that sponsors, applicants, and manufacturers of drugs, biologics, and devices are not limited solely to requesting internal supervisory review, but also have the right to request review of scientific controversies by appropriate advisory committees. FDA believes that in appropriate circumstances, advisory committees can provide the agency with useful insight and advice about the resolution of scientific controversies.

FDA initially used the direct final rule because it believed the amendment to § 10.75 was noncontroversial and in accord with FDAMA. In accordance with FDA's procedures for direct final rulemaking, the direct final rule stated that if FDA received no significant adverse comments, the direct final rule would go into effect on October 29, 1998. The direct final rule stated further that if FDA received any significant adverse comments, it would withdraw the direct final rule and consider all comments received on the companion proposed rule in the development of a final rule using the usual notice and comment rulemaking procedures. The comment period for the companion proposed rule ended on August 31, 1998. FDA received significant adverse comments in response to the direct final rule and the companion proposed rule. Therefore, in the **Federal Register** of September 23, 1998 (63 FR 50757), FDA withdrew the direct final rule.

Significant adverse comments asserted that the amendment to § 10.75 failed to provide a procedure that sponsors, applicants, and manufacturers could follow to request reviews under section 404 of FDAMA (section 404 reviews). The comments suggested that the regulation called for by section 404 of FDAMA should contain information such as the process for selecting members of an advisory committee convened to conduct a section 404 review, the timeframes for conducting the reviews, the standards for granting or denying a section 404 review, and the weight to be given to advisory committee recommendations.

In a final rule issued in the **Federal Register** on November 18, 1998 (63 FR 63978), FDA acknowledged the usefulness of much of this kind of information, but concluded that it should not be included in § 10.75. Because of the significant differences among FDA centers in applicable statutory provisions, existing appeal and dispute resolution mechanisms, and approaches to advisory committee management, FDA is adopting a center-based approach to the implementation of section 404 of FDAMA. Each affected center is responsible for developing and administering its own processes for handling requests for section 404 reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The substantive differences in the programs in the affected centers, and the different matters that could be

the subject of a request for advisory committee review, preclude inclusion of this type of information in § 10.75.

The final rule amended § 10.75 by redesignating paragraph (b) as paragraph (b)(1) and by adding paragraph (b)(2) to read as follows:

A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for such review shall be briefly set forth in writing to the requester. Persons who receive a center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

To implement the new provision and to comply with § 10.75, as amended, the Center for Devices and Radiological Health has created the Medical Devices Dispute Resolution Panel, which will operate under FDA's Medical Devices Advisory Committee. In addition to serving as a useful forum in which scientific disputes in general can be aired, the Medical Devices Dispute Resolution Panel will implement four provisions of the Federal Food, Drug, and Cosmetic Act:

(1) Section 514(b)(5)(B) of the act requires the establishment of an advisory committee to take referrals of any matter concerning the establishment, amendment, or revocation of a performance standard which requires the exercise of scientific judgment.

(2) Section 515(g)(2)(B) of the act requires the establishment of an advisory committee to take referrals of petitions for review of:

(a) the approval, denial, or withdrawal of approval of a premarket approval application, or

(b) the revocation of an approved product development protocol (PDP), a declaration that an approved PDP has not been completed, or a revocation of an approved Notice of Completion that permitted marketing of a device developed under a PDP.

(3) Section 522(b) of the act, which was added by section 212 of FDAMA, 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.

(4) Section 562 of the act 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 draft guidance document sets forth guidelines that will govern the operation of the Medical Devices Dispute Resolution Panel. Those guidelines include the appointment of a CDRH Ombudsman, who will be designated to receive, review, and make recommendations with respect to requests for review by the resolution panel. CDRH intends to ensure that a center ombudsman is in place before final guidance goes into effect.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel.'' 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, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance, consistent with GGP's.

III. Electronic Access

In order to receive ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 1121 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel,'' device safety alerts, **Federal Register** reprints, information on pre-market 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''. ''Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel'' will be available at ''http://www.fda.gov/cdrh/resolvingdisputes''.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Request for Resolution of Scientific Disputes Concerning the Regulation of Medical Devices

Description: Section 404 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) is intended to ensure that FDA has effective processes to resolve the scientific disputes that occasionally arise between FDA and the regulated industry. Section 404 added new section 562 of the act which requires FDA to establish, by regulation, a procedure under which a person who is a sponsor, applicant, or manufacturer may request a review of a scientific controversy, when no other provision of the act or regulation provides such review.

In a final rule issued in the **Federal Register** on November 18, 1998 (63 FR 63978), FDA amended 21 CFR 10.75 to reflect the provisions of FDAMA. Each affected FDA center is responsible for developing and administering its own processes for handling requests for section 404 reviews and is issuing a guidance document containing specific information of the type suggested by the comments. The draft guidance document outlines the requirements for persons who are sponsors, applicants, or manufacturers of medical devices and who wish to file a request for a review of a scientific dispute by the panel as set out in the guidance. Persons filing a request for review should provide a CDRH ombudsman with 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 all efforts that have been made to resolve the dispute, and a clear articulated summary of the arguments and relevant data and information. They may also provide material outside the official administrative record and not in the possession of FDA at the time the decision or action in dispute was made if it has a significant bearing on the issue or related public health considerations. The information that is collected will form the basis for resolving the dispute between the requester and FDA.

The likely respondents to this collection of information are medical device sponsors, applicants, or manufacturers who have a scientific dispute with FDA and who request a review of the matter by the Medical Devices Dispute Resolution Panel.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
6	1	6	20	120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The Medical Devices Dispute Resolution Panel represents a new process for resolving scientific disputes. In arriving at the estimates in Table 1 of this document for the burden imposed in connection with a request for review by the Medical Devices Dispute Resolution Panel, FDA considered the number and substance of similar appeals of various types made to FDA in recent years, knowledge of similar submissions and discussions with manufacturers.

V. Comments

Interested persons may, on or before July 26, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Written comments concerning the information collection requirements must be received by the Dockets Management Branch by June 28, 1999. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 1999.

Linda S. Kahan,

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

[FR Doc. 99–10446 Filed 4–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–3432–GN]

RIN 0938–AJ31

Medicare Program; Procedures for Making National Coverage Decisions

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice.

SUMMARY: This notice announces the process we will use to make a national coverage decision for a specific item or service under sections 1862 and 1871 of the Social Security Act. This notice will streamline our decisionmaking process and will increase the opportunities for public participation in making national coverage decisions.

EFFECTIVE DATES: This notice is effective June 28, 1999.

FOR FURTHER INFORMATION CONTACT: Ron Milhorn, (410) 786–5663; Maria Ellis, (410) 786–0309, for a graphical representation of the process.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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