Draft Guidance for Industry and Food and Drug Administration Staff - CDRH Appeals Processes

U.S. Food & Drug Administration

You should submit comments and suggestions regarding this draft document within **120** days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit e lectronic comments to http://www.regulations.gov [1]. Identify a ll comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact David S. Buckles at 301-796-5447 or by email at david.buckles@fda.hhs.gov [2].

When final, this document will supersede "Medical Device Appeals and Complaints: Guidance for Dispute Resolution," February 1998 and "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," July 2001.

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

Office of the Center Director

Preface

FDA is frequently asked about judicial remedies. A party seeking judicial review of a final action taken by FDA should consult its attorney or perform its own research of applicable statutes and regulations. It is not appropriate for FDA to offer advice or assistance concerning whether, and how, a party may seek review of an adverse decision in court. In general, FDA believes it is in the public interest for parties to avail themselves of administrative remedies first, so that FDA has the opportunity to reconsider and review any dispute concerning an FDA action before it is subject to judicial review. (See 21 CFR 10.45). In the event that a petitioner brings judicial action relating to a matter that is subject to a pending review under 21 CFR 10.75 or 10.33, or any other administrative process, the Commissioner may request that the court refer the matter back to the Agency or hold its review in abeyance pending administrative reconsideration. (See 21 CFR 10.33(h)). Moreover, the Commissioner will generally consider a petition for reconsideration only before the

petitioner brings legal action in the courts.

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[1] This applies to actions initiated by CDRH. Warning Letters or other actions taken by the other Centers, by District Offices or by the Office of Regulatory Affairs (ORA) should be submitted for review or otherwise appealed to those Offices or Centers. Warning and Untitled Letters provide a mechanism for responding to the issues, typically within 15 or 30 days. The Center expects that this mechanism will have been exhausted prior to requesting review under Section 10.75; otherwise, the request may be denied until such action has been completed.

[2] For example, a sponsor of a PMA that has been disapproved may file a petition for review of such denial on or before the thirtieth day after receipt of the notice of denial. See section 515(d)(4) of the FD&C Act.

[3] *See* 21 CFR 10.35 for requests for stays.

[4] As described in section 5 of this document, the DRP may also be convened to provide recommendations to the Office of the Commissioner on a request for reconsideration of approval or denial of a PMA.

[5] A request to convene a meeting of the DRP may also be part of a petition under 21 CFR 10.33, as described in Section 5.3.

[6] This condition may be interpreted broadly so as to allow the DRP to consider a range of issues that may be associated with a scientific dispute. For example, a scientific dispute regarding clinical evidence may also involve questions regarding the need for a training program, which could be considered by the DRP within this broader context.

[7] In preparing the final version of the Summary of Scientific Issues, the Ombudsman will take into account any comments received on the initial draft. Comments or issues raised that are not included in the final version may be captured in the administrative record of the panel proceedings.

[8] The information in the Panel Pack should conform to the recommendations in the FDA guidance document, “Advisory Committee Meetings — Preparation and Public Availability of Information Given to Advisory Committee Members” dated August 2008.

[9] At various stages in the process the Ombudsman will screen materials for inappropriate content, including, but not limited to, new information not already present in the administrative record; material concerning non-scientific issues such as regulatory and legal questions; and, personal, intemperate, or inappropriate language. The Ombudsman will request the party submitting inappropriate content to remove same. The Ombudsman will highlight any inappropriate content not removed from final materials as content the Panel members are to disregard in their deliberations.

SOURCE [3]

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