Toxicology Risk Assessment Committee #G89-1 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

General Program Memorandum G89-1

August 9, 1989

Toxicology Risk Assessment Committee

Please read the attached memorandum, endorsed by the Center Director, that proposed the establishment of a Center-wide Toxicology Risk Assessment Committee.

The primary purpose of this Committee will be to provide assessments of the potential toxic risks posed by products that are the subjects of marketing applications. The Committee will be a key element in our review process for some of the applications that present difficult toxicology questions. It will review the applications that are potentially problematic, that present sensitive, highly visible issues, or that may result in precedent-setting toxicology decisions. The Committee will also review toxicology-related product approval guidance documents.

The attached memorandum describes the operating procedures to the extent that they have been developed. Clearly, there remain some unanswered questions on selection criteria and policy issues, and the specific operating procedures are yet to be formulated. However, because of the need to expedite the formation and operation of the Committee as a working body, it is our plan to actually begin and resolve many of the open procedural questions as the Committee proceeds. The members of the initial Committee will formulate and propose specific procedures.

Listed below are the members of the initial Committee.

Jerome Donlon, OD, ODE (Co-chair)
Raju Kammula, DOED, ODE (Co-chair)
William D. Galloway, DLS, OST
Hoan-My Do Luu, DSRD, ODE
Nirmal K. Mishara, DSRD, ODE
Phyllis M. Silverman, DBS, OST
Pei Sung, DMMS, OST

Dr. Jacobson and I selected the members whose names were among those

submitted by Division Directors in ODE and OST. Because of the nature of the expertise needed on the Committee, its members will come primarily from ODE and OST. From time to time the chairperson and Committee members will rotate off the Committee, as new experts are identified and as there is a need to relieve those who have been serving for a period of time. The Committee may call upon other staff in ODE and OST for assistance as necessary.

The establishment of the Toxicology Risk Assessment Committee is effective immediately. ODE Division Directors are directed to identify applications that need its review and refer them to Dr. Donlon.

Attachment

ATTACHMENT
July 27, 1989

From: Director, Office of Device Evaluation, CDRH
Director, Office of Science and Technology, CDRH

Toxicology Risk Assessment Committee

To: Director, Center for Devices and Radiological Health, FDA
THROUGH: Deputy Director, Center for Devices and
Radiological Health, FDA /s/

Purpose

We are writing to propose the establishment of a CDRH Toxicology Risk Assessment Committee and to briefly describe its purpose and operating procedures.

Background

As you know, the Office of Device evaluation (ODE) receives a wide variety of device marketing applications that pose questions of toxic risk to patients. ODE attempts to review these with scientific rigor and consistency, although this is difficult because the toxicology expertise within ODE is dispersed among the divisions with some divisions lacking entirely in this scientific area. Additional expertise exists within OST, but at present there is no established mechanism to bring the combined expertise of ODE and OST to bear on the "tough questions" that can arise in the toxicology area, and that often cut across ODE divisions. For this reason, we propose the establishment of a central body of experts, drawn from both Officers which can be relied on as needed for expert toxic risk assessments/consultations.

Operating Procedures

The primary function of the Committee would be to provide advice to the ODE operating divisions about toxicity data as a part of the product review process. Its members would be asked to review IDE, 510(k) and PMA applications that present significant or precedent-setting toxicology questions, and to review toxicology-related product approval

guidance documents. The Committee members would be asked to render opinions, based on scientific assessments, of the potential toxic risks associated with the products under review; they would not be asked to make recommendations about product approvals. The decisions on product approvals typically would continue to be made within the ODE divisions on the basis of an evaluation of all of the device's risks and benefits.

The Committee would be composed of about seven people, primarily from ODE and OST, who are experts in toxicology, materials and statistics. We expect that the membership would rotate according to changing needs and the availability of experts. ODE and OST would jointly determine the appropriate membership.

Also, the Committee would have the prerogative of calling upon other Center resources as needed. Currently, some special government employee (SGE) toxicologists are cleared through Committee Management and are available as consultants to our advisory panels. We plan to use these individuals as resources for the Toxicology Risk Assessment Committee. The SGEs would advise this Committee in addition to reporting to the advisory panels. We expect that in some cases the Committee would report on its risk assessments during the advisory panel meetings.

We propose that the Committee be managed by ODE. The Committee would report directly to the Office of the ODE Director. However, on particular assignments it would respond to the Director of the ODE division seeking an assessment. The Committee would write its own procedures and responsibilities, with the understanding that it must usually respond to requests for reviews within two to three weeks. The risk assessments performed by the Committee will become part of the official files of the applications which are being reviewed.

The Toxicology risk Assessment Committee would not replace, nor would its function overlap with, the current PMS Toxicology Committee, which would presumably continue to serve as a forum for information exchange, problem identification, and Center-wide strategic planning. It would, however, allow for the discontinuation of ODE's Toxicology Working Group.

We believe this Committee would be comparable to the Office of

Compliance and Surveillance's (OCS's) Health Hazard Evaluation Committee, which draws its membership from other offices within the Center, and meets in response to specific needs to assess the risks caused by defective products, but is managed by OCS.

If you concur with this proposal ODE will issue the attached "blue book" policy (which will have this memorandum attached) to establish the Committee and to direct ODE Division Directors to identify applications which need review.

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)