Integrity of Data and Information Submitted to ODE #I91-2 (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.

Integrity Memorandum G91-2

May 29, 1991

Integrity Memorandum #I91-2

Integrity of Data and Information Submitted to ODE

Purpose

The purpose of this Blue Book Memorandum is to specify the procedures to be followed by the ODE staff if there is a question concerning the integrity of data and information contained in any PMA, IDE or 510(K) submission. We want to encourage reviewers to be sensitive to the possibly of inaccurate, withheld or otherwise false data in submissions reviewed by ODE. For example, the data may appear to be fabricated or the device design may suggest that the performance data are not feasible.

Procedures

If a reviewer has any suspicion concerning the integrity of data or information provided to ODE in connection with any official submission, the matter should be raised through supervisory channels to the Division Director level. If the Division Director determines that it is necessary to verify the integrity of the data or information in the submission, the Division Director should notify the ODE Integrity Coordinator. The Integrity Coordinator will discuss the matter with the appropriate Program Operations Staff Manager and, if further action is indicated, the matter will be directed to the ODE/OCS Coordinator to initiate an inspection of the person or persons responsible for the submission of the questionable data or information. A submission that is referred to OCS for verification of the data will not be cleared until the integrity of the data is established.

During the interim, the submission will be dealt with in accordance with established review procedures.

The Integrity Coordinator will keep the Director, ODE, and the appropriate Division Directors informed of any

inspections requested pursuant to these procedures.

Effective Date

These procedures are effective immediately.

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)