Meetings with the Regulated Industry #I89-3 (blue book Memo)

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.

November 20, 1989

Meetings with the Regulated Industry

Purpose.

The purpose of this memorandum is to set forth procedures to be followed when meeting with representatives of medical device firms or trade associations. As a matter of practice, ODE staff has been applying most of these principles for many years now, but they have never been formalized in a written policy or procedure.

Applicability.

The following procedures apply to all meetings with, and arranged by, ODE, including its branches, divisions, the POS staffs, and the Office of the Director. They also apply to meetings with ODE arranged by industry. They do not apply to meetings arranged by other CDRH Offices, even though ODE staff members may be present. Other CDRH Offices will have their own procedures to follow when meeting with representatives of the regulated industry.

These procedures apply to "face-to-face" meetings with representatives or employees of the "regulated industry," including a regulated firm or a trade or professional association, where the purpose of the meeting is to discuss issues related to an application or submission that a firm has or will submit to ODE or to discuss regulatory or policy issues that affect the regulated industry.

These procedures do not apply when ODE staff attends meetings of a general nature, e.g., educational or scientific meetings, or professional conventions and trade shows where, if these topics are discussed, it is done at open public sessions or in other public areas, e.g., during coffee breaks, at convention luncheons and dinners,in the exhibit hall,etc.,where meeting participants gather to discuss scientific,professional and regulatory subjects of common intellectual interest. If, however, at such meetings,shows,and conventions,these topics are the

subject of private meetings with ODE staff,all of the requirements of this memorandum apply.

This memorandum does not apply to telephone conversations with an industry representative or employee;such contacts will be the subject of a subsequent memo.

Unplanned meetings that do not conform to the requirements of this memorandum, i.e., "walk-in" meetings, are to be strongly discouraged. Such meetings may occur when, for example, a firm's representative is already in an ODE office at a properly scheduled meeting and may want to drop off information that has been requested, seek clarification about a policy or procedure, etc. This may be proper on an occasional basis. It should not be a common occurrence. Walk-in meetings should not be used to discuss the firm's pending or forthcoming submissions or other substantive issues concerning the firm without meeting the requirements of this memorandum.

Procedures.

For all "face-to-face" meetings with the regulated industry,the following procedures are to be followed:

1. Agenda. An agenda specifying the purpose of the meeting, the issues to be discussed, and the individuals who will be in attendance will be prepared prior to the meeting,and a copy placed in a division file set up for that purpose and, if applicable, a copy put in the file(s) of the submission(s) to be discussed.

2. Escorting Visitors. All non-HHS visitors coming to ODE offices for meetings should be met at the main lobby on the first floor or at the elevator lobby on the second floor by member of the division or office being visited and the visitor escorted to the sign-in log and then to the meeting room. No visitors should be left to wander around alone. If a visitor has to go to a second ODE office after the first meeting, he or she should be escorted there.

3. Sign-in Log. All non-HHS visitors coming to ODE offices for meetings should sign a visitors' log and record his or her name, the

name of the firm or organization represented, the name of the ODE employee being visited, and the purpose of the visit. This log should be maintained by each office, division, and staff, for visits to each of their areas.

4. Meeting Room. Preferably, all meetings with industry representatives should be conducted in an ODE or CDRH conference room. There are four ODE conference rooms plus conference rooms elsewhere (Office of Compliance and Surveillance) in the Piccard Building. You can reserve an ODE conference room for a meeting through the PMO office. In the unlikely event that a conference room is not available, meetings may be held in the office of a division or staff director, branch chief, or office director. In such a case, it is important that official FDA documents be protected from casual or intentional viewing by visitors. Because of the large number of documents being worked on by reviewers, visitors should not be brought into reviewers' offices.

5. ODE Attendees. At all meetings with the regulated industry, in addition to the primary reviewer who will be in attendance, the Branch Chief, Staff Director, or Division Director should be present, or, if none of these is available, at least one other ODE reviewer or Center staff member, e.g., OST scientist, should be present. The POS Director, Division Director or the Office Director may meet alone with a representative of the regulated industry if the purpose of the meeting is to discuss a management issue or personnel matter and the topics identified above are not discussed at the meeting.

6. Minutes. An ODE staff member present at the meeting should take notes of the discussion and prepare minutes of the meeting. These minutes should meet the generally accepted standard for preparation of minutes. They should be complete and concise and represent what transpired at the meeting. They should not be so detailed as to constitute a transcript of the meeting. The minutes should be reviewed and initialed by a supervisor. A copy should be placed in a division, office, or staff file set up for that purpose and, if appropriate, a copy put in the file(s) pertaining to the document(s) discussed at the meeting.

7. Document Security. All ODE offices, and especially common areas where visitors are likely to be, should be kept secure to minimize the risk of casual or intentional viewing of official FDA documents, especially, but not limited to, PMAs, IDEs, and 510(k)s.

Effective Date.

This policy is 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)