Telephone Communications Between ODE Staff and Manufacturers #I93-1 (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.

Integrity Memorandum I93-1

January 29, 1993

Integrity Memorandum #I93-1

Acting Director
Office of Device Evaluation

Telephone Communications Between ODE Staff and Manufacturers

ODE Review Staff
Through: ODE Branch Chiefs

Purpose

The purpose of this memorandum is to establish efficient and effective written procedures concerning telephone communications between manufacturers and other third parties and ODE staff members. The primary purpose of these procedures is to enable ODE personnel to use the telephone to request or obtain information necessary in the review of submissions without compromising the integrity of program activities.

Background

Over the years, ODE has had a liberal policy of open telephone communications between manufacturers and staff members in order to facilitate the review process. The use of the telephone permitted the rapid clarification of minor questions that would have taken much longer to resolve via written correspondence. This process contributed to overall efficiency in the review of submissions and reduced review times.

Over this same period of time, we have experienced an increase in the number of incoming calls initiated by manufacturers. In recent years, many of the calls from manufacturers have been to reviewers to determine the status of submissions and, because of the volume of such calls, they have become counterproductive. Also, a call to the reviewer that starts out as a status inquiry can turn into a discussion of the merits of the submission or a lobbying effort by the manufacturer's representative to obtain a favorable decision or to have a decision made by a specific time.

In addition to being a counterproductive use of limited review time, these types of telephone calls generally are inappropriate because the reviewer is asked to discuss an application without notice and, in addition, they are not fair to other manufacturers who have not called and are patiently awaiting their turn in the review process.

In addition, the agency has become increasingly concerned about inappropriate contact between reviewers and manufacturers in light of the recent unlawful gratuity cases in another agency program. The agency is also concerned about the release of financially sensitive information to unauthorized third parties, such as financial analysts, stock brokers, etc., who may use such information for financial gain through, for example, stock manipulation.

In order to avoid any appearance of favoritism, to prevent the types of problems that have been experienced elsewhere in the agency, and to re-establish the proper use of telephone communications between ODE staff and manufacturers, the following guidance is being adopted.

Telephone Policies and Procedures

A. Telephone Calls Concerning Pending Applications

1. ODE staff members may telephone manufacturers to obtain clarification or to request additional information concerning submissions under review.

ODE staff members (i.e., managers, supervisors, and reviewers) may telephone manufacturers (i.e., employees of manufacturers, their outside consultants, attorneys, and others who are authorized to speak on behalf of a manufacturer) to request, and obtain via telephone, clarification of information contained in a submission such as nonsubstantive inconsistencies, typographical errors, organization of the submission, interpretation of a graph or chart and other similar matters. The firm may supply the requested information by telephone and would not have to submit this information in writing. Obtaining such

clarification via telephone does not affect the official review clock.

ODE staff members may telephone manufacturers to request minor additions of information or minor changes to a submission, such as a change in the labeling, a change in the instructions or a change in the 510(k) summary or PMA summary provided the requested information has been documented in writing and has the concurrence of, and has been initialed by, a supervisor. This documentation will become the basis of the telephone call to the firm for the information or changes and will become a part of the official file for the submission. After the telephone discussion, the firm may then confirm the details of the conversation by telefax to ODE, if it is desirable to do so to avoid any misunderstandings because the request is complex, lengthy, or may otherwise be subject to misinterpretation. In this latter case, the reviewer will acknowledge whether the telefax is an accurate reflection of the information being requested and the telefax will become part of the administrative file for that submission. When the firm fully understands the request, the requested information must be submitted in writing and processed through the Document Mail Center as required by Blue Book Memorandum #I90-3. The effect, upon the official review clock, of making a telephone request for additional information that requires a written response depends upon the type of submission under review and the nature of the deficiencies cited. This is covered in detail in Blue Book Memorandum #I91-1, "Document Review Processing".

ODE staff members must request additional data and information in writing when the deficiencies are complex or require the submission of substantial new information such as a request that would require new clinical studies or new analyses of data and information. These written requests will be made pursuant to ODE's normal operating procedures. When desirable and after supervisory review, the information requested in an issued letter may be discussed with the firm either over the telephone or at a meeting. This can help in the clarification of the request for substantial new

information and in understanding the context of the request. This data and information must be submitted in writing by the manufacturer and processed through the Document Mail Center as required by Blue Book Memorandum #I90-3. The effect of issuing written requests for additional data and information upon the official review clock depends upon the type of submission under review and the nature of the deficiencies cited. This is covered in detail in Blue Book Memorandum #I91-1, "Document Review Processing".

Each division may provide further guidance to its staff, consistent with this memorandum, on the type of clarification that may be requested or obtained via telephone versus the type of data and information that must be requested and submitted in writing.

2. ODE staff members may accept calls from manufacturers to discuss the status of pending submissions after specified time periods in the review process have transpired, as set forth below. ODE staff members may not accept, at any time, calls from third parties, such as financial analysts, stock brokers, reporters, etc., concerning the status of submissions under review.

ODE staff members may not accept calls from manufacturers concerning the status of a pending submission if the submission is:

- an IDE that has been in ODE less than 30 days;
- a 510(k) that has been in ODE less than 90 days;
- an unfiled PMA that has been in ODE less than 45 days; or,
- a PMA or PMA supplement that has been in ODE less than 180 days.

After the foregoing time periods have transpired, ODE staff members should exercise judgment regarding the appropriateness of responding to status inquiries from

manufacturers. The ODE staff should do its utmost to be as responsive to the various publics and industry with which we deal without sacrificing valuable time and resources. For example, it would not seem appropriate to entertain repetitive inquiries concerning the status of pending submissions.

[Note: As an alternative to the receipt of telephone calls from manufacturers concerning the status of pending applications as set forth above, ODE is initiating, within the Center for Devices and Radiological Health (CDRH), a proactive communication system regarding the status of premarket approval applications, PMA supplements, and 510(k)s at selected "milestones" in the PMA/510(k) review processes. This system will be planned and developed over the next several months by an inter-office task force within CDRH. Consideration will be given to employing modern electronic communications technology such as voice mail, MCI E-mail, or other new developments suited to the purpose of keeping manufacturers updated on the status of their submissions. Furthermore, FDA is considering proposals that would specify the format, content, and timing of public status reports concerning submissions pending before the agency. These reports may include premarket approval applications, 510(k)s, as well as other pending agency actions. If the agency ultimately adopts policies or procedures respecting the public disclosure of the status of pending actions, ODE will follow such policies and procedures and this memorandum may be revised.]

3. ODE staff members may accept calls from manufacturers concerning a pending submission if the call from the manufacturer is in response to a telephone call or letter from ODE about the submission. Any manufacturer who abuses the use of the telephone by attempting to get frequent status information about a submission or by trying to improperly influence the timing or outcome of a review should be reported through supervisory channels. If this type of abuse occurs repeatedly, that manufacturer's telephone access to ODE staff members may be curtailed.

B. Other Business Telephone Calls

4. ODE staff members may accept calls from manufacturers concerning business other than a pending submission under review.

A manufacturer may initiate a call to an ODE staff member concerning business matters other than a specific submission under review, e.g., to discuss a scientific issue about a draft voluntary standard. When a manufacturer calls an ODE supervisor or manager, the person answering the call will notify the supervisor or manager who will return these calls as soon as possible. If a manufacturer calls a reviewer, the person answering the call will automatically take a message for the reviewer who will determine whether to return the call in accordance with this policy memorandum.

Unless there is a need to discuss specific, official ODE business, there is no requirement upon the part of any ODE staff member to accept or return a call from a manufacturer. This practice is necessary because of the heavy workload the ODE staff is experiencing. It is also consistent with other FDA policies designed to avoid the kind of circumstances that arose within the generic drug program.

5. Telephone calls to ODE concerning the integrity or reliability of data in submissions made to ODE should be directed to the ODE Integrity Officer.

Such telephone calls might be made by an anonymous caller or the caller might identify himself or herself. Also, the call might relate to a pending or completed submission. All such calls should be referred to the ODE Integrity Officer.

C. General Procedures

6. A written record of telephone conversations with manufacturers should be made if important for future reference.

ODE staff members should make a written record of telephone conversations with manufacturers or trade association representatives, regardless of who initiated the call. If

the purpose of the conversation was to obtain clarification on a specific submission, it is sufficient to make a record of the call along with notations on the submission itself adjacent to the matter being clarified, unless the clarification requires extensive comments. In the latter case, a separate note should be included in the file. For all other telephone conversations, staff are advised to keep a log of the telephone contacts that may be important in the future.

In such cases, the record of a telephone conversation, whether it be notations on the submission or a separate memorandum, should include the date, the name and title of the manufacturer's representative, the purpose and substance of the call, the outcome of the conversation, and the name and signature of the ODE staff member.

7. Manufacturers must identify themselves and the reason for the call.

All manufacturers calling an ODE staff member must be prepared to state their name, title, and the reason for their call, e.g., returning the call of a reviewer about 510(k) #K691005, calling to discuss a scientific issue about a draft voluntary standard or calling for clarification of a deficiency letter that requests further information.

D. Effect on Prior Policies and Guidance Memorandum

8. This guidance memorandum will have the following effect on prior Blue Book Memos.

#A86-1 (10/16/86) "Guidance on Media Contacts"

Memorandum #A86-1 is unaffected in so far as the media contact does not contravene the policy and procedures set forth in this memorandum. Record-keeping required under this guidance, in addition to the reporting required under #A86-1, applies to telephone contacts with members of the media.

#P86-2 (01/31/86) "PMA Progress Reports to Applicants"

Memorandum #P86-2 is hereby rescinded and no longer in effect.

#K89-2 (06/08/89) "Telephone Notification ... at 75 Days or Greater"

Memorandum #K89-2 is hereby rescinded and no longer in effect.

#I89-3 (11/20/89) "Meetings With Industry"

Memorandum #I89-3 is unaffected by this guidance because #I89-3 deals only with face-to-face meetings with industry. That guidance recognized that an additional memorandum would be issued to deal with telephone calls with industry, which is the purpose of this guidance.

#I90-3 (09/26/90) "Document Control Procedures"

Memorandum #I90-3 is unaffected. The coverage of "Information Received Via Telephone" as covered in that memorandum is not inconsistent with the requirements of this guidance.

#I91-1 (02/21/92) "Document Review Processing"

Memorandum #I91-1 is unaffected. The statements concerning the use of the telephone to obtain clarification provided for in that guidance memorandum are not inconsistent with the requirements of this guidance.
This guidance memorandum supersedes and hereby rescinds the interim policy established by ODE on October 21, 1992 entitled "Telephone Contact with Industry".

Effective Date

This guidance is effective immediately.

David L. West, Ph.D

More in Guidance Documents (Medical Devices and Radiation-Emitting Products)

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)