GENERAL PROCEDURAL POLICIES

INDUSTRY CONFERENCES

1. **Purpose:**

This guide establishes Center policy in scheduling and holding conferences with representatives of industry and special interest groups. This policy should be adhered to in all but the most exceptional cases.

2. **"Drop-In" Visits:**

We should generally discourage industry representatives (or the representatives of other constituencies) from "dropping in" on us. This practice not only makes us less efficient, it fosters relationships in the office that blur the distinction between our role and that of the industry representatives. It is both courteous and practical to require that at least a telephone appointment be made.

3. **Scheduling Meetings:**

a. Requests for conferences should be in writing when time allows; if not, telephone requests are acceptable if documented by a memo of telephone conversation. Adequate lead time is required to make appropriate arrangements for the meeting.

b. The following information should be provided in order to arrange for the attendance of the appropriate members of FDA.

(1) The specific subject (i.e., particular letter, NADA number, etc.).

(2) Proposed Agenda.

(3) The names and positions of industry representatives who will be attending.

c. Meetings should be scheduled within the Center's core hours of 9:30 a.m. to 3:30 p.m.

d. If the matter to be discussed at the meeting is in litigation, the Chief Counsel attorney having responsibility for the matter must be notified about the meeting request to determine if the meeting may be held.

4. **Location of Meetings:**

a. Meetings with non-government personnel should not take place in offices where trade secret or confidential information is reviewed. It is preferable that the meeting should be held in a conference room or in an office where trade secret and confidential information is not regularly reviewed.

5. **Attendance:**

a. Employees who have worked extensively on a particular matter should generally have access to meetings on that subject.

b. Supervisors who choose to limit attendance at such meetings should make their reasons explicit to any excluded employees.

c. All FDA employees should be able to find out easily when, where and with whom their colleagues are meeting. An individual's schedule of appointments should be available to fellow employees upon request.

d. At least two persons from CVM should be in attendance at all meetings with industry and special interest groups. Ordinarily this would be the reviewer responsible for the application and his/her Team Leader.

e. If the meeting involves a matter under litigation, the Chief Counsel actively having responsibility for the issue should be present. If the meeting involves legal issues other than litigation, particularly if an outside lawyer is present, CVM's Chief Counsel liaison lawyer should be invited to the meeting and be provided with background material prior to the meeting.

6. **Record Keeping:**

a. The senior member from CVM should designate a person to take notes and prepare a record of the discussion.

b. Minutes should be prepared of all conferences that involve the participation of

CVM and non-FDA personnel.

c. All FDA representatives should concur on the minutes before they are finalized. (Reference 21 CFR 10.65.)

7. **Denying Requests for Meetings**:

A request for a meeting may be denied if it would not be useful or productive (to the industry or special interest group as well as to the Center). However, the decision should be justified and supportable if it is appealed.

8. **References:**

a. 21 CFR 10.65: Meetings and correspondence.

b. Commissioner's Memorandum of 3-29-79; Our Dealings With Regulated Industry and One Another. (See Attachment A for form letter.)

FORM LETTER DESCRIBING GUIDELINES FOR MEETINGS WITH REPRESENTATIVES OF INDUSTRY OR INTEREST GROUPS

The following is a draft of a form letter to be used when scheduling conferences with representatives of a regulated industry or special interest group. This form letter should be used, with only minor editing, to set the stage for all meetings requested by industry or interest groups with policy level officers of the Center.

Dear

I will be happy to meet with you and other representatives of on .We agree that it is important for FDA to hear the views of regulated industry or interest groups on matters that may affect them. Although you have met with us before (since you have not met with us recently) it may be useful for me to set out (repeat) some very general guidelines for meetings relating to pending regulatory action.

- First, it is primarily an opportunity for you to tell us what you think. FDA's regulatory policy intentions and plans are set out in FEDERAL REGISTER documents and in other forms accessible to the public at large. For that reason, it is not appropriate for you to ask FDA for private intimations about its plans. Ne will, of course, try to be responsive to requests for clarification where you find our stated intentions obscure.

- Second, please give us an agenda listing the points you hope to cover in your presentation, as well as a list of the names and positions of the attendees. Any important additional data would also be helpful. That will help us to arrange for the attendance of the appropriate members of our own staff.

- Third, we will prepare objective and careful minutes of the meeting, and these may be available on request (except for confidential information) to interested members of the public.

- Fourth, we are precluded from receiving your views on matters in which the Commissioner is constrained to decide solely on the basis of the hearing record. Our regulations require that such discussions or views be a matter for the hearing record.

With regard to subjects that have already been acted upon, it is of course appropriate for you to ask questions regarding our administration of the law or of our regulations.

We have allowed one hour for the meeting. It will be helpful if you can plan that time carefully, allowing an appropriate time for discussion of each item, so that we can finish promptly. This policy should not be interpreted as an attempt to reduce valuable contact between FDA and industry or interest groups. Rather, it is designed to improve that relationship by clarifying our respective responsibilities, and to structure it so that the most useful advice can be made available to all parties.

We look forward to meeting with you.

Sincerely yours,

(Name)
Commissioner of Food and Drugs
(or appropriate policy-level person)