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.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date MAR 23 1987

From Director, Office of Device Evaluation

Subject Information for Executive Secretaries of ODE Advisory Panels

To See Below:

I recently met with representatives of the Health Industry Manufacturers Association (HIMA) to discuss matters relating to the Industry Representatives (IRs) on our panels. I would like to share with you some of the concerns expressed and some of the ideas they proposed. I also want to clarify and reaffirm some of our policies related to panel operations and to our relationships with the IRs.

1. HIMA is concerned that IRs may not receive information in a timely manner, that IRs may not be invited to all meetings, and that IRs may not be considered in matters such as the scheduling of meetings of the panel.

   I know that most Executive Secretaries are very careful about treating IRs as panel members due all the considerations that are extended to the voting members. At the same time, I am aware that there have been occasions when IRs have been overlooked in our administrative procedures. Therefore, I want to reaffirm that IRs are panel members, albeit non-voting members.

   Care must be taken to ensure that all panel members are considered when scheduling meetings of the panel and that all members are advised of upcoming meetings and invited to attend. General information, such as notices of meetings, information relating to the functions or procedures of the panel, information on general issues, or the public agenda, should be sent to all panel members at the same time. Any information sent to an IR is also available under Freedom of Information inquiry. Please remember, however, that the FDA Policy Board has established a policy which prohibits our distributing trade secret or confidential commercial or financial information to IRs even if they are special government employees (SGEs). They may not, for example, receive copies of premarket approval applications unless a company has released its PMA for public disclosure.

   Please ensure that all panel members are invited to meetings at which items such as panel policies and procedures, scheduling future meetings, communication, etc., are to be discussed. Matters involving specific applications or matters placed on an agenda by FDA should be discussed only during the open committee discussion or closed committee deliberations portions of a meeting.

2. HIMA wants to find a way to allow alternate IRs to attend a panel meeting in the absence of the appointed IR.

   Please adivse the IR on your panel to contact you as soon as possible after finding that he or she cannot attend a panel meeting. I do not believe that it is your responsibility to find an alternative IR for the meeting. The IR who cannot attend the meeting may attempt to find an alternate (he or she may contact the Committee Management Officer for a list of IRs appointed to other panels) or he or she may contact HIMA for help. Any alternate must be an IR who is currently appointed to one of the other ODE advisory panels. The alternate IR should contact the Executive Secretary to ensure that he or she has all the information sent to the IR (the IR should send all of the information he or she has received concerning the upcoming meeting to the alternate IR).

3. HIMA is concerned that IRs may not read the FEDERAL REGISTER Notice announcing a panel meeting and therefore suggested that written notices of a meeting be sent directly to the IR.

   If dates of future panel meetings are discussed at panel meetings, panel members should note the dates on their calendars. We should take care, however, to ensure that all panel members receive information about upcoming meetings. Thus, draft agenda items etc., should be sent to all members at the same time. If you normally contact panel members by telephone to confirm that they received copies of the agenda, etc., please ensure that you contact all panel members.

4. HIMA will request that each IR prepare a written commentary on each panel meeting.

   It is the prerogative of the IR, or any panel member, to take notes during a meeting and report and discuss panel deliberations after a meeting is completed. I recognize that HIMA is trying to improve communications between the IRs and the regulated industry. At the same time, however, please make sure that all panel members know that any problems or questions they have regarding their role on the panel, the conduct of panel meetings, specific matters before the panel, etc., should be raised at the time or brought to your attention as soon as possible. There should be no buffer between CDRH and its expert advisors in these areas.

   If the IR, or any other panel member, prepares notes or commentaries concerning issues discussed at a panel meeting and sends a copy to you or any other FDA employee, it should be incorporated into the files of the panel. Because such notes or commentaries have no official status or effect unless adopted into the official minutes by the panel, no action is required. On the other hand, if the commentary contains a significant factual error which could reflect on a panel recommendation or upon a CDRH

decision, this should be noted and placed in the panel file along with the commentary.

If a panel member prepares a minority report on an issue or enters an objection to some aspect of panel operation, these must be reviewed and considered for their potential effect on a decision. The regulation (21 CFR 14.25(i)(4)) states: "It is the responsibility of each panel member to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting the panel member attended." If a commentary were to raise issues concerning the accuracy or completeness of the official records of a panel meeting, these must be resolved by the panel. Such matters should be promptly directed to the Executive Secretary of the panel.

If the panel member does not send a copy of the note or commentary to the Executive Secretary but FDA becomes aware of the document, you should attempt to obtain a copy for inclusion in the panel record.

5. HIMA has requested copies of the official summary minutes of panel meetings and will make them available for use by the industry.

After they have been accepted by the panel and signed by the panel chairperson and the Executive Secretary, copies of the detailed minutes, with clearly identified separate descriptions of the open and closed portions of the meeting, should be sent to the Committee Management Officer (Ms. Kay Levin, HFZ-20) and to Dockets Management Branch (HFA-305). Copies should also be sent to all panel members, to consultants to the panel who attended the meeting, to my office, to the compliance liasion person, and to the Office of the Center Director. (Please see the NOTE.) A copy should be also maintained in the division files pertaining to the panel and its activities.

The IR may provide a copy of the detailed minutes he or she receives to HIMA for distribution and/or inclusion in HIMA's files. I do not believe that it is either necessary or appropriate for the Executive Secretary to maintain mailing lists of interested organizations, companies or individuals.

[PLEASE NOTE: Minutes of closed portions of panel meetings should be clearly marked "Confidential" in order to reduce the possibility of inadvertent release or disclosure. Copies of the closed portion of meetings may not be sent to non-SGE members of the panel or to the IR.]

6. HIMA noted that it is difficult at some panel meetings to determine the official voting panel members.

I believe that the procedures concerning the preparation of the Report and Recommendation of the Panel respecting the approval of the application should serve to make clear, at the time of the

vote, who is voting on each application and how they voted.

In addition, I believe that our efforts to ensure that a panel member who has a conflict of interest on a particular application does not vote or participate in the discussion on that application serve to aid in identifying official voting panel members of the panel.

We are completing work on the Executive Secretary Guidance Manual. This memorandum will be included in the manual.

I have asked Roger Barnes to serve as the ODE focal point for matters involving questions such as those in this memorandum or questions you may have concerning the activities of an Executive Secretary. Please feel free to contact him (Room 429; 427-7230).

Kshitij Mohan

Kshitij Mohan, Ph.D.