CENTER FOR DRUG EVALUATION AND RESEARCH

Guidance for Industry

The FDA published Good Guidance Practices in February 1997. This guidance was developed and issued prior to that date.

Additional copies are available from:
Office of Training and Communications
Division of Communications Management
Drug Information Branch, HFD-210
5600 Fishers Lane
Rockville, MD 20857

(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

March 15, 1989

Dear Colleague:

Undoubtedly you have read about ongoing inquiries regarding the generic drug review process. The areas being examined include impartiality of review assignments, confidentiality of applications, freedom from interruptions for reviewers, avoidance of conflicts of interest and documentation of substantive discussions with industry.

FDA Commissioner Frank Young, M.D., Ph.D. and Acting Deputy Commissioner James Benson have been very supportive and very helpful during the time of these inquiries. Under Mr. Benson's guidance, an FDA task force studied the review process and made recommendations to provide additional assurance in each area of examination.

The recommendations were given to Marvin Seife, M.D., Director of the Division of Generic Drugs, and Shrikant Dighe, Ph.D, Director of the Division of Bioequivalence. Dr. Seife and Dr. Dighe each developed plans and procedures to implement the task force recommendations for their respective divisions. This letter transmits these new procedures.

In some cases, these new procedures require adjustments, but I believe there is no choice. An example is the requirement that meetings between industry and reviewers be held in a conference room and not in a review area. Our space constraints and workload are such that applications must be stored and available in review areas. There is simply no way to hold a meeting in these areas without the visitors seeing which applications are there.

These new procedures represent the best compromise that we could make between our needs and our resources. They are being phased in as quickly as possible with the transition period being completed by April 15.

I have been charged with monitoring for compliance with these procedures and I am committed to making them work. I ask your understanding and help in this assignment. I also ask that you share this material with those who have contact with us on behalf of your firm.

Sincerely yours,

Peter H. Rheinstein, M.D.

Peter H. Rheinstein, M.D., J.D., M.S.
Director, Office of Drug Standards
Center for Drug Evaluation and Research

Recommendation:

"Work with the Office of Management and Operations to provide sufficient and convenient meeting space for the Divisions of Generic Drugs and Bioequivalence, so that meetings with industry are held outside the immediate work space of ANDA reviewers."

Implementation Plan

Meetings with industry or other non-FDA representatives should be held away from reviewing areas and away from even casual access to abbreviated new drug applications (ANDAs) or abbreviated antibiotic drug applications (AADAs). A conference room has been set up in room 17-B-06 for this purpose as an interim measure until more suitable accommodations can be made. If more space is needed, or if more than one meeting is scheduled at the same time, other available conference rooms should be used.

Visitors should not be allowed past secretaries in the review areas. Outer areas where visitors may enter should be free from visible ANDA or AADA information (e.g., applications should be stored so that firm and product identifiers are not in plain sight).

Recommendation

"Ensure that a supervisor is present when ANDA reviewers meet with industry representatives to discuss their applications (to both lessen pressure on the reviewer and provide confirmation of the meeting's substance)."

Implementation Plan

A reviewer should not meet with industry representatives to discuss applications unless the supervisor is in attendance or, if the supervisor is not available, another supervisor, a consumer safety officer (CSO), or another reviewer might be the other division attendee. Likewise, when a supervisor meets with industry, a reviewe or other division employee should also be in attendance.

When meetings with industry are held, a written record must be prepared summarizing major issues or recommendations of the meeting. It is not expected that every detail of all topics discussed be a pa of the record. We suggest the form, Record of Telephone Conversation/Meeting (Form FD 2587) be used to record the meeting. A notebook or folder holding such records must be maintained by each supervisor. The Division Director/Deputy Director shall periodicall review the meeting records and make recommendations as appropriate.

Each Branch shall continue to maintain a "sign-in log" for industry representatives.

In responding to an application status request, the CSO should determine: the ANDA number; name, strength, and dosage form of the drug product; date and nature of the last FDA letter; and the date and nature of the firm's response to FDA's letter. The CSO should inform the industry representative that he/she will look into the situation and that the division will respond, by letter, when the review of the submission is completed. The CSO should not divulge whether any specific portions of the review have been completed.

When a telephone call from an industry representative is received in a review branch, division staff should use the following procedures. The secretary (or person answering the telephone) should ascertain if the person calling is an industry representative. If so, the call should be referred to the review branch chief, who will determine if the inquiry is a status or technical call. Status calls should be referred to a CSO. Technical inquiries should be responded to by the branch chief, in consultation with the reviewer, if necessary. It is appropriate that the branch chief convey major problems found in the subject application to the firm, if any are known.

Recommendation

"Controls should be increased over the assignment of new applications."

Implementation Plan

New applications (for products never before received in the Division of Generic Drugs) are assigned to a particular Chemistry Review Branch after discussion between the Division Director and the Chief of the Review Support branch. The assignment to a particular Chemistry Review Branch is usually based on previously submitted applications for similar drug products. Generally, subsequent applications for the same drug product are assigned to that same Chemistry Review Branch. All branch assignments are reviewed by either the Chief or Deputy Chief of the Review Support Branch.

The application is then forwarded to the Chief of the assigned Chemistry Review Branch for assignment of a chemistry reviewer. Likewise, the application is assigned a labeling reviewer by the Chief of the Labeling Review Branch. These assignments are based on the individual reviewer's current workload and expertise with that product.

After all assignments to reviewers are made, the Division Director and Deputy Director independently examine the assignment of reviewers to assure that the assignments are appropriate. This multi-level review gives increased assurance that assignments are made appropriately. The Division Director initials the ANDA assignment record.

M E M O R A N D U M

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Drug Standards

DATE : March 14, 1989

TO : Division Staff

FROM : Director
Division of Bioequivalence (HFD-250)

SUBJECT: Implementation of Recommendations for the Generic Review Process

The Commissioner's Office requested that a thorough review of the ANDA review process be conducted. The report of the study group which conducted the review recommends a number of actions to be taken to make the process more efficient and effective. The Commissioner has endorsed the report and its recommendations. The following recommendations of the study group are to be implemented immediately by the Division of Bioequivalence.

Recommendation:

"Work with the Office of Management and Operations to provide sufficient and convenient meeting space for the Divisions of Generic Drugs and Bioequivalence, so that meeting with industry are held outside the immediate work space of ANDA reviewers."

Implementation Plan

All meetings with industry or other non-FDA representatives must be held away from reviewing areas and away from access to ANDA jackets and other confidential commercial information. To facilitate implementation of this recommendation in the immediate future, a small room in 17B-06 will be available as a conference room as an interim measure until more suitable accommodations are found. If more space is needed, meetings will be scheduled in other available conference rooms.

Recommendation:

"Ensure that a supervisor is present when ANDA reviewers meet with industry representatives to discuss their applications (to both lessen pressure on the reviewer and provide confirmation of the meetings substance)."

Recommendation:

"Review and update written guidance to reviewers and suppport staff on responding to industry request for meetings, or similar demands. The guidance should be applicable to all review divisions within the Agency".

Implementation Plan

The Division of Bioequivalence will cooperate with the Center in reviewing and updating written guidance to reviewers and support staff on responding to industry request for meeting, or similar demand. The Division is prepared to nominate one or two reviewers for this purpose.

Recommendation:

"Controls should be increased over the assignment of new applications".

Implementation Plan

All ANDA submissions are assigned to reviewers by two branch chiefs working as a team. This system of assigning review work has worked well and ensures equitable distribution of work among the three branches. The current team assignment system will continue without any changes.

Recommendation:

"Protect reviewers from having to answer application "status" calls from manufacturers, by assigning such duties to consumer safety officers."

Implementation Plan

The Division of Bioequivalence does not have a CSO. The Division of Bioequivalence is presently working with the Division of Human Resources Management to hire a CSO for the purpose of answering application "status" calls from the industry. Reviewers and secretaries will then be able to refer calls from the industry to the CSO.

Presently, "status calls" will be handled by the Branch Chief until a CSO is selected.

Recommendation:

"Prepare written Standard Operating Procedures on the review of ANDAs by the Division of Generic Drugs, to be followed by reviewers and their supervisors."

RECORD OF TELEPHONE CONVERSATION/MEETING

DATE

NDA NUMBER

IND NUMBER

TELECON/MEETING

INITIATED BY

- ☐ APPLICANT/ SPONSOR
- ☐ FDA

MADE

- ☐ BY TELEPHONE
- ☐ IN PERSON

PRODUCT NAME

FIRM NAME

NAME AND TITLE OF PERSON WITH WHOM CONVERSATION WAS HELD

TELEPHONE NO.

SIGNATURE

DIVISION

FORM FD 2587 (11/77)

ORIGINAL IND/NDA

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