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

AUG 18 1995

TO ALL ANDA AND AADA APPLICANTS

Dear Sir or Madam:

The purpose of this letter is to bring to your attention two developments that are important to individuals and firms associated with the generic drug industry.

In September 1994, the Food and Drug Administration's Center for Drug Evaluation and Research (CDER) adopted the International Conference on Harmonization (ICH) stability testing recommendations for New Drug Substances and Products. The agency's agreement with ICH to harmonize stability testing recommendations is limited to applications for new molecular entities. However, the Office of Generic Drugs (OGD) will now accept for abbreviated applications the ICH recommendations for **long-term** room temperature conditions for stability studies--25±2°C, 60±5%RH. OGD also will continue to accept any studies conducted at the conditions it has recommended in the past, 25-30°C/ambient humidity.

The ICH recommendations for temperature and humidity for **accelerated** stability studies in support of room temperature labeling statements for abbreviated applications are the same as OGD's current recommendations--40±2°C, 75±5%RH.

The second development involves bioequivalence protocols and other nonapplication specific correspondence that come to OGD's Division of Bioequivalence (DOB). The Office is experiencing a significant increase in requests to review bioequivalence study protocols. These protocols tend to be for drug products that have several years of remaining patent life. Because these protocols often are for drug products that have not been previously reviewed by OGD, significantly more time is required to evaluate and provide comment.

While protocols do not have any regulatory time requirements for action, OGD generally has tried to provide comments within approximately 60-90 days of receipt. However, because of the volume of protocols requiring review, the backlog of studies and other information submitted in support of pending applications is beginning to be adversely affected. Based on the need to balance regulatory review requirements for applicants and to provide comment on protocols submitted by interested parties, OGD will set the following review priorities for protocols:

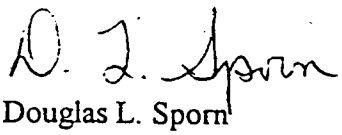
Drug products with 3 years or less of remaining patent protection will be generally reviewed within 90 - 120 days of submission.

Drug products with greater than 3 years of remaining patent life will be generally reviewed within 120 - 180 days.

I am urging you and others in the industry to be aware of OGD's review priorities and time frames when planning to submit protocols. Recognizing the time required for OGD to complete the review of protocols should allow firms to more accurately plan for future scheduling of bioequivalence studies. OGD will, of course, continue to develop and issue bioequivalence guidances in an effort to aid the industry and reduce the number of protocols submitted to the Office.

Similarly the increasing number of letters requesting written comment or recommendations on other matters is impacting the Division capacity to review studies and other work related to pending applications. It often requires a substantial amount of time to develop a response to these letters. While OGD believes that it is important to maintain this system of communication, it is also necessary that the focus of our resources remain devoted to application reviews. OGD will continue to strive for timely responses, but review of applications is the first priority. Consequently, responses to letter may take longer than has been the case in the past.

Sincerely yours,



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Center for Drug Evaluation and Research