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

January 15, 1993

TO ALL ANDA AND AADA APPLICANTS

Dear Sir or Madam:

In a letter dated July 27, 1992, Jane E. Henney, M.D., Deputy Commissioner for Operations of the Food and Drug Administration (FDA) notified drug manufacturers and industry associations that the Generic Drug Enforcement Act of 1992 (GDEA) was enacted. The letter described new certification and information requirements for drug product applications. The requirements went into effect on June 1, 1992. The letter also provided guidance on how to comply with the new requirements.

In accordance with the new requirements of GDEA, the Office of Generic Drugs (OGD) intends to refuse to file or approve submissions that require the new information but do not contain it.

Refusal to File

Effective 40 days after the date of this letter, OGD will no longer accept for filing abbreviated applications that do not contain the following information:[1]

1. Certification About the Use of a Debarred Person

   A certification "...that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) [section 306(a) or (b)], in connection with such application." [Section 306(k)(1) of the GDEA (21 U.S.C. 335a(k)(1)).]

2. List of Relevant Convictions for Persons Debarred or Not Debarred

   A list of all relevant convictions of the applicant and affiliated persons responsible for the development or submission of the application. See Dr. Henney's July 27, 1992, letter for a description of affiliated persons (copy

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[1]Supplements to abbreviated new drug applications (ANDA's) or abbreviated antibiotic applications (AADA's) that provide for a different or additional use of a drug (i.e., supplements that provide for a use not covered by the listed drug and are supported by new clinical studies, not literature references) also require this information. However, OGD does not formally "refuse to file" any supplement.

attached). Please also note that contractors responsible for the development of data and other information used to support approval of an application are affiliated persons. Relevant convictions are those for which a person can be debarred as described in section 306(a) and (b). The list must contain all such convictions that occurred within five years before the date of the application. [See section 306(k)(2) of the GDEA.]

Firms with no convictions to list should submit a statement to that effect.

Refusal to Approve

Effective immediately, OGD will refuse to approve ANDA's, AADA's, and the applicable supplements described in footnote 1 of this letter received on or after June 1, 1992, that do not have the certification and list of convictions described above.

1. Submissions Pending at the Agency

   If the affected submission currently is pending with the agency and OGD reviews it before you amend with the required information, OGD will issue a not approvable letter, citing the failure to provide this information as a deficiency along with other deficiencies, if any.

2. Submissions at the Firm

   If the affected submission currently is with you, include this information in your amendment responding to a prior not approvable letter or telephone call notice of deficiency. Otherwise, after OGD reviews the amendment, it will issue a not approvable letter citing the failure to provide the certification and list of convictions as a deficiency, along with other deficiencies, if any.

If you have any questions or comments about the Center for Drug Evaluation and Research's implementation of the GDEA, please call (301-295-8041) or write to the Division of Regulatory Affairs at the following address: 7500 Standish Place, Rockville, Maryland 20855.

Sincerely yours,

Roger L. Williams

Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research