PHARMACEUTICAL SCIENCES

AVAILABILITY OF LABELING GUIDANCES

CONTENTS

PURPOSE This MAPP outlines revisions to the system for announcing and attaining labeling guidances which are prepared by the Office of Generic Drugs (OGD) and are to be made available to assist the public in the preparation of package insert labeling for proposed abbreviated new drug or antibiotic applications (ANDA/AADA).

BACKGROUND

- The OGD and the former Division of Generic Drugs have been providing *labeling guidelines* for multisource drug products since the late 1970s. However, the preparation and availability of the guidelines have varied, depending to a great extent upon available resources and office review priorities.

- Due to the complexity of contemporary labeling practice and the changes occurring regarding patent and exclusivity issues, industry is interested in having OGD provide guidance on the preparation of package insert labeling.

REFERENCES

- Federal Food, Drug, and Cosmetic Act, as Amended § 505(j)(2)(A)(v)
- Code of Federal Regulations 21 CFR § 1.3 (a); 1.3 (b); 314.94(a) (8); and 314.3 (b)
- Office of Generic Drugs, Policy and Procedure Guide # 19 - 90 (April 12, 1990)

DEFINITIONS

- **Abbreviated Application.** An application described under 21 CFR 314.94, including all amendments and supplements to the application. The term applies to both an abbreviated new drug application and an abbreviated antibiotic application.
- **Labeling.** All written, printed, or graphic matter accompanying an article at any time such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce [see 21 CFR 1.3(a)].
- **Label.** Any display of written, printed, or graphic matter on the immediate container of any article [see 21 CFR 1.3(b)].

POLICY

- The OGD will issue labeling guidances that have been prepared by its Labeling Review Branch, Division of Labeling and Program Support.
- Guidances will be issued depending upon variables such as the difficulty in preparing satisfactory labeling for an ANDA from innovator product labeling, patent and exclusivity issues in the innovator's labeling, multiple dosage forms, and/or when it anticipates many ANDA submissions that involve a particular labeling issue.
- The team leader of the Labeling Review Branch, or his or her designee, will mail the requested guidance to the requestor, within ten working days of the receipt of the request.
- Only those guidances that meet an immediate need should be requested. No more than ten guidances will be mailed to a requestor at any one time.

RESPONSIBILITIES

The Labeling Review Branch is responsible for:

- preparing new labeling guidances and updating existing guidances on a timely basis.
- maintaining a file of labeling guidances.
- providing a printed copy of a guidance(s) or an electronically formatted disk (if available) upon written request.
- providing quarterly updates to the responsible person in CDER to update Internet and CDER's Fax-on-Demand system.

PROCEDURES

For Guidances:

- A labeling reviewer will prepare the guidances, under the direction of the team leader of the Labeling Review Branch, using the format defined in 21 CFR 201.56 and 21 CFR 201.57, and using the most recently approved labeling of the listed drug.
- The team leader of the Labeling Review Branch, and the director, Division of Labeling and Program Support will review and approve the guidances. During the review process, specific issues may be consulted to other program areas within OGD or the Center.
- A brief summary will be included to indicate those areas of the guidance that were changed. The summary will be located at the end of the guidance.
- The reviewer will complete a memorandum , citing important issues in the development of the guidance, and it will contain signature concurrence of the team leader and the division director. This portion of the document will not be released to the public.
- Guidances released to the public will be dated, but unsigned. Certain guidances, including all future guidances, will be available on an electronically formatted disk.

Preparing the List:

- The team leader of the Labeling Review Branch will prepare and update quarterly a list of all current guidances, noting the date of the most recent revision, which guidances are new, and which are available on Internet and CDER's Fax-on-Demand.

- A cover memorandum will accompany each list and will provide directions to the requestor.

Obtaining the List and/or Guidances:

- Copies of the Labeling Guidance List may be acquired:

  1. from the Freedom of Information Staff (HFD-19);

  2. by accessing Internet through the World Wide Web at WWW.FDA.GOV (go to the CDER section); or,

  3. by accessing CDER's Fax-on-Demand System (1-800-342-2722).

- To obtain a specific guidance(s), the requestor should:

  1. mail or fax (1-301-594-0180) a copy of the List, with specific guidances circled, to:

     Office of Generic Drugs
     Attn: Team Leader, Labeling Review Branch, HFD-638
     7500 Standish Place
     Rockville, MD 20855

  2. access Internet through the World Wide Web at WWW.FDA.GOV (go to the CDER section); or,

  3. access CDER's Fax-on-Demand System (1-800-342-2722).

EFFECTIVE DATE

This MAPP is effective immediately.