

SUPPLEMENTAL POLICIES

UNIFORMITY IN LABELING

The basic purpose of labeling is to enable drugs to be used safely and effectively by lay persons in the case of OTC products, or by veterinarians in the case of prescription items. The user has a right to expect that the same sort of information will be given for all drugs with similar activities. For this reason, uniformity goes beyond the mere physical layout of the labeling. The approved labeling establishes the limits for journal advertising, promotional material, mailing pieces, and verbal representations by the drug firm's detail person. Because of this, a uniform approach to labeling is required.

1. Purpose:

This guide provides criteria to facilitate the consistent and uniform application of policies relating to the review and evaluation of drug labels and labeling.

2. General Policy:

It is the policy of the Center to apply labeling requirements to manufacturers and distributors of drugs as uniformly as possible, particularly where the same drug is under review.

3. Principles of Uniformity:

The following standard is applied to the evaluation of information to be included in labeling: Claims of effectiveness of the drug for any particular indication are subjected to the rigorous criteria of "substantial evidence;" on the other hand, information on adverse reactions may be included if only a probable or even possible causal relationship is established. Relatively precise standards can be established for the former; the latter is frequently a matter of medical judgment. However, the concept of uniformity still applies.

- a. Labeling proposed in an original or supplement to an NADA should be compared with previously approved labeling, if any, for the same or similar drugs. This comparison will assure inclusion of all significant precautionary information appearing in the previously approved labeling, if it is applicable to the labeling under

consideration. Further, information included in the new application or supplement could signal the need for initiating labeling changes to update previously approved labeling.

- b. Identical compounds with different trade names should contain labeling that is substantially the same, although under present regulations the wording may vary. For example, circumstances that constitute a "CONTRAINDICATION" for the use of a drug under the one trade name shall not be presented in the "PRECAUTIONS" section of the labeling of the same compound under a different trade name.
- c. The labeling of a drug belonging to a class of drugs containing many individual drug products with the same or similar indications should contain all of the cautionary statements and adverse reaction information appropriate to that class of drugs unless adequate evidence has been offered that the subject drug product should be labeled differently.
- d. When a labeling requirement applies to an entire class of drugs, the requirement should be considered as the basis for a regulation.