§ 201.12 Definitions of some terms used in this chapter.

201.21 "Intended use."—The term "intended use" means the use for which the drug is intended, including the conditions, purposes, or uses for which the drug is prescribed, recommended, or suggested to be used, except that such statements shall not refer to conditions, uses, or purposes for which the drug can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

201.22 "Inert ingredient."—The term "inert ingredient" means any ingredient which is not a component of the therapeutic regimen of the drug, whether added to the formulation as a single substance or in admixture with other substances.

201.23 "Proprietary name."—The term "proprietary name" means a name, whether or not it includes the name of a drug or ingredient, which is assigned to the manufacturer, producer, or distributor for the purpose of identifying the drug or ingredient and which is not a Latin or vernacular name of the substance as such or a name which is derived from such a name.

201.24 "Prescription drug."—The term "prescription drug" means a drug other than a nonprescription drug, which requires a prescription for its purchase by a consumer.

201.25 "Prescription writing."—The term "prescription writing" means any writing or document to which is affixed the signature of a practitioner, evidencing the authorization of the drug by the practitioner for the use of a consumer.

201.26 "Review date."—The term "review date" means the date on which the review of the drug by the Agency is to begin or which the Agency is required to have completed by a specified date.

§ 201.6 Drugs; misleading statements.

(a) Among representations in the labeling of a drug which render such drug misbranded is a false or misleading representation with respect to another drug or a device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason, among other reasons, of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

[41 FR 6908, Feb. 13, 1976]

§ 201.10 Drugs; statement of ingredients.

(a) The ingredient information required by section 502(e) of the Federal Food, Drug, and Cosmetic Act shall appear together, without any intervening written, printed, or graphic matter, except the proprietary names of ingredients, which may be included with the listing of established names, and such statements that are specifically required for certain ingredients by the act or regulations in this chapter.

(b) The term "ingredient" applies to any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances.

(c) The labeling of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of the ingredients present in the drug appear in the labeling, or the relative prominence otherwise given such names.

(2) Failure to reveal the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is material in the light of the representation that such ingredient is present in such drug.

(3) The employment of a fanciful proprietary name for a drug or ingredient in such a manner as to imply that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug or ingredient is a common substance, the limitations of which are readily recognized when the drug or ingredient is listed by its established name.

(4) The featuring in the labeling of inert or inactive ingredients in a manner that creates an impression of value greater than their true functional role in the formulation.

(5) Designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.

(d)(1) If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in...