- (b) If its labeling or packaging fails to conform with the requirements of Section 191A of this subheading.
- (2) If in package form, unless it bears a label containing the name and place of business of the manufacturer, packer, or distributor.
- (3) If any word, statement, or other information required by or under authority of this subheading to appear on the label or labeling is not prominently placed thereon with conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in terms to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca leaves, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as, habit forming, by regulations issued by the Secretary under this subheading, or by regulations issued pursuant to Section 502 352 (d) of the Federal Act, unless its label bears the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."
- If it is a drug, unless (a) its label bears, to the exclusion of any other non-proprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii) in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: provided, that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subsection, shall apply only to prescription drugs; and (b) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; provided, however, that to the extent that compliance with the requirements of clause (a) (ii) or clause (b) of this subparagraph is impracticable, exemptions shall be allowed under regulations promulgated by the Secretary, or under the Federal Act.
- (6) As used in paragraph (5) of this section the term "established name," with respect to a drug or ingredient thereof, means (a) the applicable official name designated pursuant to Section 508 358 of the Federal Act, or (b) if there is no such name and the drug or ingredient is an article recognized in an official compendium, then the official title thereof in the compendium or (c) if neither clause