a. By adding a heading to paragraph (b) (3) and by revising subdivisions (i) and (ii) thereunder, as follows:

(3) Adequate information for use in drug package:

(i) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use including indications, effects, dosages, routes, methods, and frequency and duration of administration, and all side effects, hazards, warnings, precautions and contraindications under which practitioners licensed by law to administer the drug can use the drug safely and for all purposes for which it is intended, including all purposes for which it is advertised or represented; and

(ii) If the article is subject to section 505 or 507 of the act, the labeling incorporating such information is the labeling approved or permitted under the provisions of section 505 or 507, respectively.

b. By revising paragraph (b) (4) to read as follows:

(4) Promotional labeling options and requirements.

(i) *When required.* All matter determined under § 1.105(1) to the labeling as defined in section 201(m) of the act shall conform to one of the following options unless it is subject to the requirements of subparagraph (3) of this paragraph or optionally conforms to such requirements:

(*a*) "*Full Disclosure.*" (*1*) All labeling disseminated by or on behalf of the manufacturer, packer, or distributor of the drug purporting to present adequate information for its use, or intended for employment as a reference to drug-use information, incorporates as an integral part of such labeling adequate "full disclosure" information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and all side effects, hazards, warnings, precautions, and contraindications under which practitioners licensed by law to administer the drug can use the drug safely and for all purposes for which it is intended, including all purposes for which it is advertised or represented; and

(*2*) If the article is subject to section 505 or 507 of the act, the labeling incorporating such information is substantially the same as the labeling approved or permitted under the provisions of section 505 or 507, respectively.

(*b*) "*Full Warning Disclosure.*" Unless such labeling is subject to or optionally conforms to the requirements of subparagraph (3) of this paragraph or (*a*) of this subdivision, if the labeling:

(*1*) Recommends or suggests a drug dosage; or

(*2*) Presents information for drug use relating to one or more selected indications, but not all indications; or

(*3*) In the case of brochures, booklets, mailing pieces, and related presentations is of more than three pages,

the labeling shall present with respect to each indication for use of the drug suggested in such labeling, substantially the same information for its use, including effects, dosages, routes, methods, and frequency and duration of administration as the corresponding information in the approved or permitted drug package labeling, and shall incorporate as an integral part of such labeling a "Full Warning Disclosure"; i.e., substantially the same information concerning all side effects, hazards, warnings, precautions, and contraindications as that in the approved or permitted drug package labeling.

(*c*) "*Brief Summary.*" Unless such labeling is subject to, or optionally conforms to the requirements of subparagraph (3) of this paragraph or (*a*) or (*b*) of this subdivision, the labeling shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section, side effects and contraindications include side effects, hazards, warnings, precautions, and contraindications), and effectiveness of the drug, if the labeling recommends or suggests any indication for use in words or by written, printed, or graphic matter, or contains any claim for safety or effectiveness.

(*d*) *Reminder labeling.* If the labeling is not subject to the requirements of subparagraph (3) of this paragraph or (*a*), (*b*), or (*c*) of this subdivision, so-called reminder labeling may be employed. Such labeling may contain the name of a drug (which necessitates declaring the established name, if any, naming a dosage form, and furnishing its quantitative ingredient information) and information relating to quantity, price, and the name of the manufacturer, packer, or distributor, but shall contain no other information or representation in words or by means of graphic matter.