formation in brief summary relating to side effects, contraindications, and effectiveness whether or not it relies on a distinct part of the advertisement to present information relating to side effects and contraindications.

(ii) The information relating to effectiveness may be limited to the effectiveness and limitations of the effectiveness of the drug in the conditions for which it is recommended or suggested in the advertisement.

(iii) The information relating to side effects and contraindications shall disclose all of the side effects and contraindications pertinent to the uses of the drug dosage form(s) recommended or suggested in the advertisement, all other uses for which the advertised dosage form is commony prescribed, and all other uses for which such dosage form(s) is recommended or suggested in any labeling or advertising disseminated by or on behalf of the manufacturer, packer, or distributor of the drug.

(3) *Substance of information to be included in brief summary.* (i) (*a*) An advertisement for a prescription drug covered by a new-drug application approved pursuant to section 505 of the act after October 10, 1962, or any approved supplement thereto, shall not recommend or suggest any use that is not in the labeling accepted in such approved new-drug application or supplement. The advertisement shall present information from labeling approved or permitted in a new-drug application concerning all side effects and contraindications mentioned in such labeling; each side effect and contraindication idea in the labeling shall be contained in the advertisement.

(*b*) If a prescription drug was covered by a new-drug application or a supplement thereto that became effective prior to October 10, 1962, an advertisement may recommend or suggest:

(*1*) Uses contained in the labeling accepted in such new-drug application and any effective or approved supplement thereto.

(*2*) Additional uses contained in labeling in commercial use on October 9, 1962, to the extent that such uses did not cause the drug to be an unapproved "new drug" as "new drug" was defined in section 201(p) of the act as then in force, and to the extent that such uses would be permitted were the drug subject to subdivision (iii) of this subparagraph.

(*3*) Additional uses contained in labeling in current commercial use to the extent that such uses do not cause the drug to be an unapproved "new drug" as defined in section 201(p) of the act as amended. The advertisement shall present information from such labeling concerning all side effects and contraindications mentioned in such labeling.

(ii) An advertisement for a prescription drug subject to certification under section 507 of the act shall not recommend or suggest any use that is not in the labeling covered by the certification or covered by the applicable certification regulations or regulations providing for exemption from certification. The advertisement shall present information from such labeling covered by the certification, or the applicable certification regulations, or regulations provided for exemption from certification, concerning all side effects and contraindications mentioned in such labeling and such regulations.

(iii) In the case of an advertisement for a prescription drug other than a drug the labeling of which causes it to be an unapproved "new drug" and other than drugs covered by subdivisions (i) and (ii) of this subparagraph, an advertisement may recommend and suggest the drug only for those uses contained in the labeling thereof:

(*a*) For which the drug is generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs; or

(*b*) For which there exists substantial evidence of safety and effectiveness, consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of the drug involved, on the basis of which it can fairly and responsibly be concluded by such experts that the drug is safe and effective for such uses; or

(*c*) For which there exists substantial clinical experience, adequately documented in medical literature or by other data (to be supplied to the Food and Drug Administration, if requested), on the basis of which it can fairly and responsibly be concluded by qualified experts that the drug is safe and effective for such uses; or

(*d*) For which safety is supported under any of the preceding clauses in (*a*), (*b*), and (*c*) of this subdivision and effectiveness is supported under any other of such clauses.