

The advertisement shall present information concerning all of the side effects and contraindications that are pertinent to the uses of the drug recommended or suggested in the advertisement, all other uses for which the dosage from advertised is commonly prescribed, and all other uses for which such dosage form is recommended or suggested in all labeling and/or advertising disseminated by or on the behalf of the advertiser. The information relating to effectiveness shall include specific indications for use of the drug for purposes claimed in the advertisement; for example, when an advertisement contains a broad claim that a drug is an antibacterial agent, the advertisement shall name the types of infections and micro-organisms for which the drug is effective clinically, consistent with the information required or permitted in the drug package labeling.

(4) *"True statement" of information.* An advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if:

- (i) It contains any untrue statement; or
- (ii) It fails to present adequately a fair balance between claims for safety or effectiveness of the drug and information relating to the limitations of safety or effectiveness pertinent to the uses of the drug; or
- (iii) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement or under such conditions of use as are customary or usual; or

(iv) It is misleading in any other particular.

(5) *False, lacking in fair balance, or otherwise misleading advertisement.* An advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, among other reasons, if it:

(i) Contains a representation or suggestion, not approved or permitted for use in the drug package labeling, that a drug is better, more effective, useful in a broader range of conditions or patients, safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence, whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

(ii) Contains a drug comparison claiming advantages for a drug without simultaneously disclosing any pertinent disadvantages (including, for example, disclosure of the fact that the advertised drug has the other disadvantages of a category of drugs and additional disadvantages).

(iii) Contains favorable information or opinions about a drug previously regarded as valid but which have been rendered obsolete by contrary and more recent information, or fails to contain significant recent literature references that are less favorable to a drug than older references used.

(iv) Contains information from published articles that report no side effects with a drug but fails to contain significant information from the literature or other sources that report side effects, or otherwise selects information from any source in a way that makes a drug appear to be safer than it is.

(v) Contains information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does.

(vi) Contains literature references or representations that may exaggerate the effectiveness of a drug by failure to disclose the extent to which claimed results may be due to placebo effect or concomitant therapy.

(vii) Contains data or conclusions from studies of a drug in animals or in vitro in a way that suggests they represent clinical studies, or in a way that suggests they have clinical significance when in fact no such clinical significance has been demonstrated.

(viii) Contains information from published or unpublished reports or opinions erroneously represented or suggested to be authentic or authoritative.

(ix) Contains information or an opinion from a recognized authority or based on a study favorable to a drug, but fails to reveal that such information or opinion is contrary to or inconsistent with information or opinions from other recognized authorities or other reliable studies.

(x) Uses a statement by a recognized authority that is apparently favorable about a drug, but fails to use unfavorable data or statements from the same authority.

(xi) Contains information or conclusions from a study that lacks significance because it was uncontrolled or for other reasons.