

(xii) Uses a quote or paraphrase out of context to convey a false or misleading idea.

(xiii) Uses literature quotations or references that purport to support an advertising claim but in fact do not support the claim or have relevance to the claim.

(xiv) Uses literature, quotations, or references to recommend or suggest conditions of drug use that are not approved or permitted in the drug package labeling or for which there is insufficient evidence to establish safety and effectiveness.

(xv) Offers a combination of drugs for the treatment of patients suffering from a condition amenable to treatment by any of the components rather than for patients who require concomitant therapy as provided by the fixed combination drug, unless approved or permitted drug package labeling recommends the drug for such use.

(xvi) Uses a study on a small number of patients or on normal subjects without disclosing the limitations of the study by calling attention to the small number of patients or the fact that the subjects were normal.

(xvii) Uses "statistics" on numbers of patients, or counts of favorable results or side effects, derived by pooling data from various insignificant or dissimilar studies in a way that suggests that such "statistics" are valid or are derived from large or significant studies supporting favorable conclusions.

(xviii) Uses the concept of "statistical significance" to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results.

(xix) Uses statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies the design or protocol of which are not amenable to formal statistical evaluations.

(xx) Uses inversely or otherwise erroneously a statistical finding of "no significant difference" to claim clinical equivalence or to deny or conceal the potential existence of a real clinical difference.

(xxi) Uses tables or graphs to distort or misrepresent the relationships, trends, differences, or changes among the variables or products studied, or uses graphs that are not appropriately titled; for example, fails to label abscissa and ordinate so that the graph is not readily interpretable without reference to the text.

(xxii) Uses reports or statements represented to be statistical analyses, interpretations, or evaluations that are inconsistent with or violate the established principles or statistical theory, methodology, applied practice, and inference, or that are derived from clinical studies, the design, data, or conduct of which substantially invalidate the application of statistical analyses, interpretations, or evaluations.

(xxiii) Uses statements or representations that a drug differs from or does not contain a named drug or category of drugs, or that it has a greater potency per unit of weight, in a way that suggests erroneously or without substantial evidence that the advertised drug is safer or more effective than such other drug or drugs.

(xxiv) Contains claims concerning the mechanism or site of drug action that are not supported by substantial evidence.

(xxv) Uses those parts or the whole of studies or reports of studies that include dosages in excess of those authorized in approved package labeling if the drug advertised is subject to section 505 or 507 of the act, or in the case of other drugs, if the dosages employed were in excess of those recommended in the labeling and generally recognized as safe.

(xxvi) Uses misleading headline, subheadline, or pictorial or other written, printed, or graphic matter.

(xxvii) Fails to present the pertinent limitations of the effectiveness of the drug in immediate conjunction with and as prominently as any claim for effectiveness, whether or not such limitations are disclosed in another part of the advertisement.

(xxviii) Fails to present with equal prominence the limitations of safety of the drug; for example, specific side effects or contraindications pertinent to any claim for safety in immediate conjunction with each such claim for safety even though such limitations are disclosed in another part of the advertisement.

(xxix) Fails to present information concerning side effects and contraindications in as much depth and detail (not exceeding that required in the drug