(*e*) *Price list or catalog.* Labeling that incorporates the name of a drug, dosage form name, and quanitative ingredient information with similar information for other drugs in a composite price list or catalog, but does not recommend or suggest any indication for use, or dosage for use of the drug, or contain any information regarding frequency or duration of administration or any claim for safety, effectiveness, or other quality of the drug, is not required to include information relating to side effects and contraindications.

(*f*) *Motion picture films, film strips, sound recordings, and related audio or visual promotional labeling.* (*1*) Motion picture films, film strips, sound recordings, and related audio or visual presentations by or on behalf of the manufacturer, packer, or distributor of a drug that promote the use of a drug distributed by such a person, irrespective of whether the drug is named specifically or is in a category of drugs named, shall present, unless it conforms to the requirements of subparagraph (3) of this paragraph or (*a*), (*b*), or (*c*) of this sub-division, as an integral part of such audio or visual presentation information relating to the major side effects and contraindications of such drug. The audio or visual presentation shall close with a statement to the effect that the drug has side effects and contraindications in addition to those mentioned in the presentation and that "full disclosure" information to supplement the audio or audio-visual presentation will be presented to the audience in printed form. If the drug is subject to section 505 or 507 of the act, the information relating to the major side effects and contraindications of the drug is information that is approved or permitted by written notification from the Food and Drug Administration for such use in motion picture films, film strips, sound recordings, and related audio or visual promotional labeling under the provisions of section 505 or 507, respectively: *Provided, however,* That the requirement that information relating to the major side effects and contraindications of a drug be presented as an integral part of audio or visual promotional labeling will be met in the case of such labeling produced prior to the effective date of this requirement if such information is added to the end of the audio or visual presentation, and if information relating to any major side effects and contraindications acquired after production of the audio or visual promotional labeling is added to the end of the audio or visual presentation.

(*2*) Audio and audio visual aids that are generally promotional, in the sense that they relate to a class of drugs one member of which is marketed by the firm sponsoring the preparation or the presentation of the film or recording, become product labeling when used in a promotional setting (such as when used by detail men), when associated with product promotional pieces, or when other means are used to associate the general message with a particular product in the class.

c. By adding to the proposed revision of paragraph (b)(4) above new subdivisions (ii), (iii), (iv), and (v) that would be similar with respect to labeling as proposed § 1.105(e) (2), (3), (4), and (5) above would be for advertising.

d. By inserting the following subdivisions after § 1.106(b) (4)(v) as contemplated in proposal "c" above.

(—) Fails to incorporate as an integral part of any labeling, required information relating to side effects and contraindications; for example, the required information shall be incorporated in the audio or visual elements of films or sound recordings, bound as an integral part of a reprint, printed on the reverse side of a letter, etc.; provided, however, that in the case of an exhibit, this requirement will be met if a "Brief Summary" of side effects and contraindications is presented on at least one panel of the exhibit, other panels bear a prominent reference to the presence and location of the "Brief Summary" on the exhibit, and drug package or other "Full Disclosure" labeling is made available to viewers at the exhibit.

(—) Fails to present in the case of motion picture films, film strips, sound recordings, and related audio or visual promotional labeling, required information relating to side effects and contraindications so that it will be seen or heard with a prominence reasonably comparable to the information relating to effectiveness of the drug, taking into account all implementing factors such as space, timing, and audio-visual or any other techniques apt to achieve emphasis.

(—) Disseminates reprints of literature reports, reports of symposia, or other reports that include claims of effectiveness or safety or recommend or suggest conditions of use of the drug not approved or permitted in the drug package labeling unless such representations are excluded prior to dissemination.