package) as claims for effectiveness or safety of the drug, taking into account the length of the advertisement and the nature of its message. This means that there may be two permissive levels of summarization:

(*a*) If the claims for effectiveness or safety are presented briefly without dosage information and the advertisement as a whole appears on three pages or less, the side effects and contraindications may be presented concisely provided that each such idea expressed in the approved or permitted drug package labeling is presented in a "Brief Summary"; or

(*b*) If the claims for effectiveness or safety are presented in detail or in discussion form, or dosage information is presented, or parts of the advertisement appear on more than three pages of a periodical of page size larger than 50 square inches, or more than four pages of a periodical of 50 square inches or smaller page size, the side effect and contraindication information shall be presented as a "Brief Discussion Summary" comparable in depth and detail with the information required in the drug package labeling under § 1.106(b)(3).

(xxx) Fails to provide sufficient emphasis for the information relating to side effects and contraindications contained in a distinct part of an advertisement by reason of repetition or other emphasis in that part of the advertisement of claims for effectiveness or safety of the drug.

(xxxi) Fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(xxxii) Fails to present on a page facing another page (or on another full page) of an advertisement on more than one page, information relating to side effects and contraindications when such information is in a distinct part of the advertisement.

(xxxiii) Fails to provide adequate emphasis by the use of borders, headlines, or other copy that extends across the gutter for the fact that two facing pages are part of the same advertisement, when one page contains information relating to side effects and contraindications.

(xxxiv) Fails to include on each spread of an advertisement of more than one page a prominent reference to the presence and location of the information relating to side effects and contraindications when presented as a distinct part of an advertisement.

(f) Revoked.

(g) Revoked.

(h) Revoked.

(i) Revoked.

* * * * * * *

(l)(1) Advertisements subject to section 502(n) of the act include advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communications systems.

(2) Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter concerning a drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor, including reference publications (for example, the Physicians' Desk Reference) for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug, are regarded as labeling not subject to section 502(n) of the act, but subject to the labeling requirements of § 1.104 and § 1.106 (b) or (c).

B. Under the authority vested in the Secretary by the act (secs. 502(f)(1), (n), 701(a), 52 Stat. 1051, as amended 76 Stat. 791; 1055; 21 U.S.C. 352(f)(1), (n), 371(a)) and delegated as cited above, it is proposed that:

1. Section 1.105 *Prescription-drug advertisements* be amended by adding to the end of paragraph (d)(2) a new sentence reading "The requirement that an advertisement name at least one dosage form and furnish the related quantitative ingredient information for a drug does not apply to advertisements promoting the sale of a drug in bulk for use in the manufacture of another drug or for use as a component in prescription compounding.".

2. Section 1.106 *Drugs and devices; directions for use* be amended: