(The document referred to follows:)

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE—FOOD AND DRUG ADMINISTRATION

Prescription drug advertising and labeling regulations

[21 CFR Part 1]

NOTICE OF PROPOSED RULE MAKING

On the basis of experience with and in response to requests from the pharmaceutical manufacturing industry for clarification of the regulations concerning prescription drug advertisements (§ 1.105) and the regulations establishing exemptions from the requirement that prescription drug labeling bear adequate directions for use (§ 1.106 (b) and (c)), the Commissioner of Food and Drugs proposes the amendments set forth below.

A. Under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502(n), 701(e), 52 Stat. 1050, as amended 76 Stat. 791; 1055 as amended 70 Stat. 919; 21 U.S.C. 352(n), 371(e)) and delegated by him to the Commissioner (21 CFR 2.120), it is proposed that § 1.105 be amended by revising paragraph (e) and (l) and by revoking paragraphs (f), (g), (h), and (i). The revised paragraphs would read as follows:

§ 1.105 Prescription-drug advertisements.

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(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(1) *When required.* (i) Any advertisement for a prescription drug shall present a true statement of information in brief summary relating to side effects, contraindications (when used in this section, side effects and contraindications include side effects, hazards, warnings, precautions, and contraindications), and effectiveness, if the advertisement recommends or suggests any indication for use in words or by written, printed, or graphic matter, or suggests a dosage for use of the drug (other than quantitative ingredient information), or contains any claim for safety or effectiveness.

(ii) A so-called "reminder advertisement" may be employed if it contains only the name of a drug (which necessitates declaring the established name ,if any, naming a dosage form, and furnishing its quantitative ingredient information) and information relating to quantity, price, and the name and address of the manufacturer, packer, or distributor. To qualify for exemption from the requirements of subdivision (i) of this subparagraph, the advertisement shall not recommend or suggest by printing or graphics any indication for use, drug dosage, or claim for safety, effectiveness, or other quality of the drug.

(iii) An advertisement that incorporates the name of a drug, dosage form name, and quantitative ingredient information, with similar information for other drugs in a composite price list, but does not recommend or suggest any indication for use or dosage for use of the drug, is not required to include information relating to side effects, contraindications, and effectiveness.

(iv) An advertisement for a drug sold in bulk packages, in accordance with the practice of the trade, solely to be processed, manufactured, labeled, or repacked in substantial quantities, is not required to include a statement of information relating to side effects, contraindications, and effectiveness if it does not contain claims for the therapeutic safety or effectiveness of the drug.

(v) An advertisement for a drug sold for use as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions, and which otherwise complies with the conditions for the labeling exemption contained in § 1.106(k), is not required to include a statement of information relating to side effects, contraindications, and effectiveness if it does not contain claims for the therapeutic safety or effectiveness of the drug.

(2) *Scope of information to be included in brief summary.* (i) The advertisement as a whole and each representation and suggestion in the advertisement shall be consistent with the requirement that it present a true statement of in-