

## Food and Drug Administration, HHS

## § 369.4

(1) and (12) of this section may be placed on the shielded container only.

[40 FR 31308, July 25, 1975, as amended at 40 FR 44543, Sept. 29, 1975; 42 FR 15674, Mar. 22, 1977; 43 FR 14646, Apr. 7, 1978; 46 FR 8955, Jan. 27, 1981; 49 FR 44460, Nov. 7, 1984; 50 FR 8996, Mar. 6, 1985; 55 FR 11582, Mar. 29, 1990; 56 FR 10806, Mar. 14, 1991; 67 FR 4907, Feb. 1, 2002]

### **PART 369—INTERPRETATIVE STATEMENTS RE WARNINGS ON DRUGS AND DEVICES FOR OVER-THE-COUNTER SALE**

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369.20 Drugs; recommended warning and caution statements.

369.21 Drugs; warning and caution statements required by regulations.

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371.

SOURCE: 39 FR 11745, Mar. 29, 1974, unless otherwise noted.

#### **Subpart A—Definitions and Interpretations**

##### **§ 369.1 Purpose of issuance.**

The warning and caution statements suggested in subparts B and C of this part, for inclusion in the label or labeling of drugs and devices subject to section 502(d) and (f)(2) and other relevant provisions of the Federal Food, Drug, and Cosmetic Act are issued for the purpose of assisting industry in preparing proper labeling for these articles for over-the-counter sale and in meeting the legal requirements of the

act that the label or labeling of drugs and devices bear adequate warnings, in such manner and form as are necessary for the protection of users. Only section 502(d) of the act requires use of the specific language included in these suggested warning and caution statements. These suggested warning or caution statements are illustrative of those that may be necessary or desirable. It is the responsibility of the manufacturer, packer, shipper, or distributor in interstate commerce to see that such statements are adequate for compliance with the provisions of the law. Omission of any article from this suggested list does not relieve drugs and devices subject to provisions of the act from bearing adequate warning or caution statements where such statements are necessary or desirable for the protection of the user.

##### **§ 369.2 Definitions.**

(a) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act.

(b) The terms *drugs* and *devices* are defined in section 201(g) and (k) of the act.

(c) Official compendia are defined in section 201(j) of the act.

##### **§ 369.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).**

Drugs exempted from prescription-dispensing requirements under section 503(b)(1)(C) of the act are subject to the labeling requirements prescribed in § 310.201(a) of this chapter. Although, for convenience, warning and caution statements for a number of the drugs named in § 310.201 of this chapter (cross-referenced in the text of this part) are included in subpart B of this part, the inclusion of such drugs in §§ 369.20, 369.21, 369.22 in no way affects the requirements for compliance with § 310.201(a) of this chapter, or the provisions of an effective application pursuant to section 505(b) of the act.

##### **§ 369.4 Warnings suggested for drugs by formal or informal statements of policy.**

The warning and caution statements included in subpart B of this part in no