

injection, it need not be named. *Provided, however,* That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, the information required by paragraphs (f) (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

### Subpart A—Definitions and Interpretations

Sec.

- 369.1 Purpose of issuance.
- 369.2 Definitions.
- 369.3 Warnings required on drugs exempted from prescription-dispensing requirements of section 503(b)(1)(C).
- 369.4 Warnings suggested for drugs by formal or informal statements of policy.
- 369.6 [Reserved]
- 369.7 Warnings required by official compendia.
- 369.8 Warning statements in relation to conditions for use.
- 369.9 General warnings re accidental ingestion by children.
- 369.10 Conspicuousness of warning statements.

### Subpart B—Warning and Caution Statements for Drugs

- 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.

EDITORIAL NOTE: Nomenclature changes to part 369 appear at 69 FR 13717, Mar. 24, 2004.

### 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 label-

ing 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

## Food and Drug Administration, HHS

## § 369.20

§ 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 way affect any warning statement suggested for such drugs or devices by any statement of policy or interpretation in subchapter C of this chapter.

[39 FR 11745, Mar. 29, 1974, as amended at 40 FR 13496, Mar. 27, 1975]

### § 369.6 [Reserved]

### § 369.7 Warnings required by official compendia.

Any drug included in the official compendia defined by the act shall bear such warning or caution statement as may be required by such compendia, and no statement in subpart B or subpart C of this part is intended to alter, modify, or permit the omission of any such statement required by such compendia.

### § 369.8 Warning statements in relation to conditions for use.

The mention in any warning or caution statement included in subparts A, B, and C of this part, of a disease condition does not imply a finding on the part of the Food and Drug Administration that any drug or device is efficacious in such condition; nor is any drug or device bearing labeling referring to such disease condition precluded from regulatory action under the applicable provisions of the act if such claim is considered to be misbranding.

### § 369.9 General warnings re accidental ingestion by children.

Section 369.20 includes under certain items, but not all medicines, the statement: "Keep this and all medicines out of children's reach. In case of overdose, get medical help or contact a Poison Control Center right away," or "Keep out of reach of children." However, in view of the possibility of accidental ingestion of drugs, it is not only suggested but is recommended that one of

these statements be used on the label of all drug products.

[64 FR 13296, Mar. 17, 1999]

### § 369.10 Conspicuousness of warning statements.

Necessary warning statements should appear in the labeling prominently and conspicuously as compared to other words, statements, designs, and devices, and in bold type on clearly contrasting background, in order to comply with the provisions of section 502(c) and (f)(2) of the act. The warning statements should be placed in the labeling in juxtaposition with the directions for use and, in any case, should appear on the label when there is sufficient label space in addition to mandatory label information.

## Subpart B—Warning and Caution Statements for Drugs

### § 369.20 Drugs; recommended warning and caution statements.

ACETANILID.

*Warning*—Do not exceed recommended dosage. Overdosage or continued use may result in serious blood disturbances.

ACETOPHENETIDIN CONTAINING PREPARATIONS. (See § 201.309 of this chapter.)

*Warning*—This medication may damage the kidneys when used in large amounts or for a long period of time. Do not take more than the recommended dosage, nor take regularly for longer than 10 days without consulting your physician.

ANESTHETICS FOR EXTERNAL USE (LOCAL ANESTHETICS). (See also § 310.201(a)(19) and (23) of this chapter.)

*Caution*—Do not use in the eyes. Not for prolonged use. If the condition for which this preparation is used persists or if a rash or irritation develops, discontinue use and consult physician.

ANTIHISTAMINICS FOR EXTERNAL USE (EXCEPT PREPARATIONS FOR OPHTHALMIC USE).