should be used and any or all of the additional indications for sunscreen drug products may be used.

(c) **Warnings.** The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings section of the applicable OTC drug monographs unless otherwise stated in this paragraph (c).

(1) **For combinations containing a skin protectant and a sunscreen identified in §§347.20(d) and 352.20(b).** The warnings for sunscreen drug products in §352.60(c) of this chapter are used.

(2) **[Reserved]**

(d) **Directions.** The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) **For combinations containing a skin protectant and a sunscreen identified in §§347.20(d) and 352.20(b).** The directions for sunscreen drug products in §352.60(d) of this chapter are used.

(2) **[Reserved]**

PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

348.1 Scope.

348.3 Definitions.

Subpart B—Active Ingredients

348.10 Analgesic, anesthetic, and antipruritic active ingredients.

Subpart C—Labeling

348.50 Labeling of external analgesic drug products.


**SOURCE:** 57 FR 27656, June 19, 1992, unless otherwise noted.