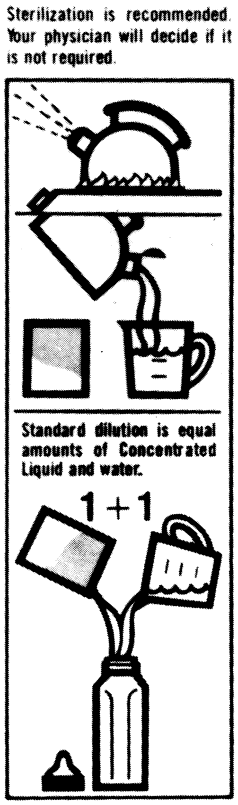
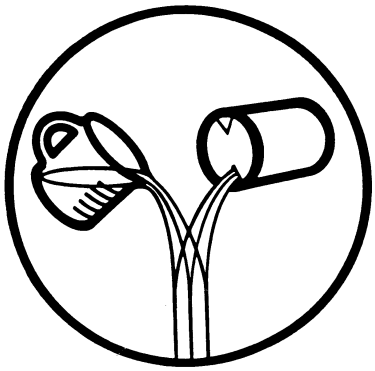


(c) A ''Use by _____'' date, the blank to be filled in with the month and year selected by the manufacturer, packer, or distributor of the infant formula on the basis of tests or other information showing that the infant formula, until that date, under the conditions of handling, storage, preparation, and use prescribed by label directions, will: (1) when consumed, contain not less than the quantity of each nutrient, as set forth on its label; and (2) otherwise be of an acceptable quality (e.g., pass through an ordinary bottle nipple).

(d) The statement ''Add Water'' or ''Do Not Add Water'', as appropriate, to appear on the principal display panel of concentrated or ready-to-feed infant formulas. In close proximity to the statement ''Add Water'', a symbol such as



if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.

(e) A warning statement beneath or in close proximity to the ''Directions For Preparation and Use'' that cautions against improper preparation or use of an infant formula, such as ''THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE''.

(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as ''USE AS DIRECTED BY A PHYSICIAN''.

[50 FR 1840, Jan. 14, 1985, as amended at 67 FR 9585, Mar. 4, 2002]

§ 107.30 Exemptions.

When containers of ready-to-feed infant formula, to be sold at the retail level, are contained within a multiunit package, the labels of the individual containers shall contain all of the label information required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act), §§ 107.10 and 107.20, and all appropriate sections of part 101 of this chapter, except that the labels of the individual containers contained within the outer package shall be exempt from compliance with the requirements of section 403 (e)(1) and (i)(2) of the act; and §§ 107.10 (a) and (b)(2) and 107.20 (b), (e), and (f), provided that (a) the multiunit package meets all the requirements of this part; (b) individual containers are securely enclosed within and are not intended to be separated

from the retail package under conditions of retail sale; and (c) the label on each individual container includes the statement ''This Unit Not Intended For Individual Sale'' in type size not less than one-sixteenth inch in height. The word ''Retail'' may be used in lieu of or immediately following the word ''Individual'' in the statement.

Subpart C—Exempt Infant Formulas

§ 107.50 Terms and conditions.

(a) *Terms and conditions.* Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low brith weight or who otherwise has an unusual medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

(b) *Infant formulas generally available at the retail level.* (1) These exempt infant formulas can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, even though such formulas may also be represented and labeled for use in clinically serious or life-threatening disorders.

(2) Except as provided in paragraphs (b)(4) and (5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control procedure requirements of part 106, and the labeling requirements of subpart B of this part.

(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in paragraph (e)(1) of this section, on or before May 21, 1986, or on or before the 90th day before the first processing of the infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under paragraph (d) of this section.

(4) To retain the exempt status of an infant formula covered by this paragraph, when any change in ingredients or processes that may result in an adverse impact on levels of nutrients or availability of nutrients is instituted, the manufacturer shall submit to FDA at the address specified in paragraph (e)(1) of this section, before the first processing of the infant formula, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, a detailed description of the reformulation and the rationale for the reformulation, a complete description of the change in processing, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review that information under paragraph (d) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (b)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragraph (d) of this section.

(c) *Infant formulas not generally available at the retail level.* (1) These exempt infant formulas are not generally found on retail shelves for general consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening