food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this subparagraph, the term "children" means individuals who are under the age of twelve years.

(b) Labeling and advertising requirements for foods

(1) A food to which this section applies shall not be deemed under section 343 of this title to be misbranded solely because its label bears, in accordance with section 343(i)(2) of this title, all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 321(ff) of this title except as a part of a list of all the ingredients of such food, and (ii) unless such ingredients are listed in accordance with applicable regulations under section 343 of this title. To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(c) Definitions

(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

(2) For purposes of paragraph (1)(B)(i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 343(j) of this title insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, overweight, underweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

1 So in original. Probably should be “paragraph".

§ 350a. Infant formulas

(a) Adulteration

An infant formula, including an infant formula powder, shall be deemed to be adulterated if—

(1) such infant formula does not provide nutrients as required by subsection (i) of this section,

(2) such infant formula does not meet the quality factor requirements prescribed by the Secretary under subsection (b)(1) of this section, or

(3) the processing of such infant formula is not in compliance with the good manufacturing practices, and the quality control procedures prescribed by the Secretary under subsection (b)(2) of this section.

(b) Requirements for quality factors, good manufacturing practices, and retention of records

(1) The Secretary shall by regulation establish requirements for quality factors for infant formulas to the extent possible consistent with current scientific knowledge, including quality factor requirements for the nutrients required by subsection (i) of this section.

(2)(A) The Secretary shall by regulation establish good manufacturing practices for infant formulas, including quality control procedures that the Secretary determines are necessary to as-
§ 350a

The Secretary shall by regulation re-
quire that the manufacturer of an infant for-
mula test each batch of such formula for such
new nutrient in accordance with subparagraph
(A), (B), or (C).

(E) For purposes of this paragraph, the term
"final product stage" means the point in the
manufacturing process, before distribution of an
infant formula, at which an infant formula is
homogenous and is not subject to further de-
gradation.

(4)(A) The Secretary shall by regulation estab-
lish requirements respecting the retention of
records. Such requirements shall provide for—

(i) the retention of all records necessary to
demonstrate compliance with the good manu-
facturing practices and quality control proce-
dures prescribed by the Secretary under para-
graph (2), including records containing the re-

(ii) regularly scheduled testing, by the man-
ufacturer of an infant formula or an agent of
such manufacturer, of samples of infant for-
mulas during the shelf life of such formulas to
ensure that such formulas are in compliance
with this section,

(iii) in-process controls including, where
necessary, testing required by good manufactur-
ing practices designed to prevent adultera-
tion of each batch of infant formula, and

(iv) the conduct by the manufacturer of an
infant formula or an agent of such manufac-
turer of regularly scheduled audits to deter-
mine that such manufacturer has complied
with the regulations prescribed under subpar-
agraph (A).

In prescribing requirements for audits under
clause (iv), the Secretary shall provide that such
audits be conducted by appropriately trained in-
dividuals who do not have any direct respon-
sibility for the manufacture or production of in-
fant formula.

(B) Each nutrient premix used in the manufac-
ture of an infant formula shall be tested for each
relied upon nutrient required by subsection (i) of
this section which is contained in such premix
to ensure that such premix is in compliance
with its specifications or certifications by a pre-
mix supplier.

(C) During the manufacturing process or at
the final product stage and before distribution of an
infant formula, an infant formula shall be
tested for all nutrients required to be included in
such formula by subsection (i) of this section for
which testing has not been conducted pursu-
ant to subparagraph (A) or (B). Testing under
this subparagraph shall be conducted to—

(i) ensure that each batch of such infant for-
mula is in compliance with the requirements
of subsection (i) of this section relating to
such nutrients, and

(ii) confirm that nutrients contained in any
nutrient premix used in such infant formula
are present in each batch of such infant for-
mula in the proper concentration.

(D) If the Secretary adds a nutrient to the list
of nutrients in the table in subsection (i) of this
section, the Secretary shall by regulation re-
such person intends to manufacture such new infant formula, and
(B) such person has at least 90 days before marketing such new infant formula, made the submission to the Secretary required by subsection (c)(1) of this section.

(2) For purposes of paragraph (1), the term “new infant formula” includes—
(A) an infant formula manufactured by a person which has not previously manufactured an infant formula, and
(B) an infant formula manufactured by a person which has previously manufactured infant formula and in which there is a major change, in processing or formulation, from a current or any previous formulation produced by such manufacturer.

For purposes of this paragraph, the term “major change” has the meaning given to such term in section 106.30(c)(2) of title 21, Code of Federal Regulations (as in effect on August 1, 1986), and guidelines issued thereunder.

(d) Submission of information about new infant formula required
(1) A person shall, with respect to any infant formula subject to subsection (c) of this section, make a submission to the Secretary which shall include—
(A) the quantitative formulation of the infant formula,
(B) a description of any reformulation of the formula or change in processing of the infant formula,
(C) assurances that the infant formula will not be marketed unless it meets the requirements of subsections (b)(1) and (1) of this section, as demonstrated by the testing required under subsection (b)(3) of this section, and
(D) assurances that the processing of the infant formula complies with subsection (b)(2) of this section.

(2) After the first production of an infant formula subject to subsection (c) of this section, and before the introduction into interstate commerce of such formula, the manufacturer of such formula shall submit to the Secretary, in such form as may be prescribed by the Secretary, a written verification which summarizes test results and records demonstrating that such formula complies with the requirements of subsections (b)(1), (b)(2)(A), (b)(2)(B)(i), (b)(2)(B)(ii), (b)(3)(A), (b)(3)(C), and (1) of this section.

(3) If the manufacturer of an infant formula for commercial or charitable distribution for human consumption determines that a change in the formulation of the formula or a change in the processing of the formula may affect whether the formula is adulterated under subsection (a) of this section, the manufacturer shall, before the first processing of such formula, make the submission to the Secretary required by paragraph (1).

(e) Additional notice requirements for manufacturer
(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer—
(A) may not provide the nutrients required by subsection (i) of this section, or
(B) may be otherwise adulterated or misbranded,
the manufacturer shall promptly notify the Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary.

(2) For purposes of paragraph (1), the term “knowledge” as applied to a manufacturer means (A) the actual knowledge that the manufacturer had, or (B) the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care.

(f) Procedures applicable to recalls by manufacturer; regulatory oversight
(1) If a recall of infant formula is begun by a manufacturer, the recall shall be carried out in accordance with such requirements as the Secretary shall prescribe under paragraph (2) and—
(A) the Secretary shall, not later than the 15th day after the beginning of such recall and at least once every 15 days thereafter until the recall is terminated, review the actions taken under the recall to determine whether the recall meets the requirements prescribed under paragraph (2), and
(B) the manufacturer shall, not later than the 14th day after the beginning of such recall and at least once every 14 days thereafter until the recall is terminated, report to the Secretary the actions taken to implement the recall.

(2) The Secretary shall by regulation prescribe the scope and extent of recalls of infant formulas necessary and appropriate for the degree of risks to human health presented by the formula subject to the recall.

(3) The Secretary shall by regulation require each manufacturer of an infant formula who begins a recall of such formula because of a risk to human health to request each retail establishment at which such formula is sold or available for sale to post at the point of purchase of such formula a notice of such recall at such establishment for such time that the Secretary determines necessary to inform the public of such recall.

(g) Recordkeeping requirements for manufacturer; regulatory oversight and enforcement
(1) Each manufacturer of an infant formula shall make and retain such records respecting the distribution of the infant formula through any establishment owned or operated by such manufacturer as may be necessary to effect and monitor recalls of the formula. Such records shall be retained for at least one year after the expiration of the shelf life of the infant formula.

(2) To the extent that the Secretary determines that records are not being made or maintained in accordance with paragraph (1),
Secretary may by regulation prescribe the records required to be made under paragraph (1) and requirements respecting the retention of such records under such paragraph. Such regulations shall take effect on such date as the Secretary prescribes not sooner than the 180th day after the date such regulations are promulgated. Such regulations shall apply only with respect to distributions of infant formulas made after such effective date.

(h) Exemptions; regulatory oversight

(1) Any infant formula which is represented and labeled for use by an infant—
   (A) who has an inborn error of metabolism or a low birth weight, or
   (B) who otherwise has an unusual medical or dietary problem,

is exempt from the requirements of subsections (a), (b), and (c) of this section. The manufacturer of an infant formula exempt under this paragraph shall, in the case of the exempt formula, be required to provide the notice required by subsection (e)(1) of this section only with respect to adulteration or misbranding described in subsection (e)(1)(B) of this section and to comply with the regulations prescribed by the Secretary under paragraph (2).

(2) The Secretary may by regulation establish terms and conditions for the exemption of an infant formula from the requirements of subsections (a), (b), and (c) of this section. An exemption of an infant formula under paragraph (1) may be withdrawn by the Secretary if such formula is not in compliance with applicable terms and conditions prescribed by this paragraph.

(i) Nutrient requirements

(1) An infant formula shall contain nutrients in accordance with the table set out in this subsection or, if revised by the Secretary under paragraph (2), as so revised.

(2) The Secretary may by regulation—
   (A) revise the list of nutrients in the table in this subsection, and
   (B) revise the required level for any nutrient required by the table.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Minimum*</th>
<th>Maximum*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protein (gm)</td>
<td>1.8 b</td>
<td>4.5</td>
</tr>
<tr>
<td>Fat:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>gm</td>
<td>3.3</td>
<td>6.0</td>
</tr>
<tr>
<td>percent cal</td>
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<td>54.0</td>
</tr>
<tr>
<td>Essential fatty acids:</td>
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</tr>
<tr>
<td>mg</td>
<td>300.0</td>
<td></td>
</tr>
<tr>
<td>Vitamins:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A (IU)</td>
<td>250.0</td>
<td>(75 µg)</td>
</tr>
<tr>
<td>D (IU)</td>
<td>40.0</td>
<td>100.0</td>
</tr>
<tr>
<td>K (µg)</td>
<td>4.0</td>
<td>100.0</td>
</tr>
<tr>
<td>E (IU)</td>
<td>0.7</td>
<td>(with 1.7 IU/gm linoleic acid).</td>
</tr>
<tr>
<td>C (ascorbic acid)</td>
<td>8.0</td>
<td></td>
</tr>
<tr>
<td>B1 (thiamine) (µg)</td>
<td>40.0</td>
<td></td>
</tr>
<tr>
<td>B2 (riboflavin) (µg)</td>
<td>60.0</td>
<td></td>
</tr>
</tbody>
</table>

* Stated per 100 kilocalories.

The source of protein shall be at least nutritionally equivalent to casein.

Required to be included in this amount only in formulas which are not milk-based.

Calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0.

as par. (1), substituted ‘‘paragraph (2)’’ for ‘‘subsection (a)(2)’’ of this section, substituted a period for the colon after ‘‘as so revised’’, and added par. (2).

**Effective Date of 1980 Amendment**

Section 6 of Pub. L. 96–359 provided that: ‘‘Section 412 of the Federal Food, Drug, and Cosmetic Act (added by section 2) [this section] shall apply with respect to infant formulae manufactured on or after the 90th day after the date of the enactment of this Act [Sept. 26, 1980].’’

§ 350b. New dietary ingredients

(a) In general

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 342(f) of this title unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) Petition

Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of title 5, the decision of the Secretary shall be considered final agency action.

(c) Notification

(1) In general

If the Secretary determines that the information in a new dietary ingredient notification submitted under this section for an article purported to be a new dietary ingredient is inadequate to establish that a dietary supplement containing such article will reasonably be expected to be safe because the article may be, or may contain, an anabolic steroid or an analogue of an anabolic steroid, the Secretary shall notify the Drug Enforcement Administra-

tration of such determination. Such notification by the Secretary shall include, at a minimum, the name of the dietary supplement or article, the name of the person or persons who marketed the product or made the submission of information regarding the article to the Secretary under this section, and any contact information for such person or persons that the Secretary has.

(2) Definitions

For purposes of this subsection—

(A) the term ‘‘anabolic steroid’’ has the meaning given such term in section 802(41) of this title; and

(B) the term ‘‘analogue of an anabolic steroid’’ means a substance whose chemical structure is substantially similar to the chemical structure of an anabolic steroid.

(d) ‘‘New dietary ingredient’’ defined

For purposes of this section, the term ‘‘new dietary ingredient’’ means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.


**AMENDMENTS**

2011—Subsecs. (c), (d). Pub. L. 111–353 added subsec. (c) and redesignated former subsec. (c) as (d).

**GUIDANCE**

Pub. L. 111–353, title I, § 113(b), Jan. 4, 2011, 124 Stat. 3921, provided that: ‘‘Not later than 180 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall publish guidance that clarifies when a dietary supplement ingredient is a new dietary ingredient, when the manufacturer or distributor of a dietary ingredient or dietary supplement should provide the Secretary with information as described in section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350b(a)(2)], the evidence needed to document the safety of new dietary ingredients, and appropriate methods for establishing the identify [sic] of a new dietary ingredient.’’

**Construction of 2011 Amendment**

Nothing in amendment by Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, to alter jurisdiction and authorities established under certain other Acts, or in a manner inconsistent with international agreements to which the United States is a party, see sections 2206, 2251, and 2252 of this title.

§ 350c. Maintenance and inspection of records

(a) Records inspection

(1) Adulterated food

If the Secretary has a reasonable belief that an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary,