(B) recommending measures for protecting the integrity of the infant formula supply and preventing contamination;

(C) outlining methods to incentivize new infant formula manufacturers to increase supply and mitigate future shortages; and

(D) recommending other necessary authorities to gain insight into the supply chain and risk for shortages, and to incentivize new infant formula manufacturers.

(k), (*l*) Omitted

(m) Importation for personal use

(1) In general

Notwithstanding any provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), during the 90-day period beginning on December 29, 2022, an individual may, without prior notice to the Food and Drug Administration, import up to a 3-month supply of infant formula for personal use from—

(A) Canada;

(B) any country in the European Union; or

(C) any other country that is determined by the Secretary to be implementing and enforcing requirements for infant formula that provide a similar assurance of safety and nutritional adequacy as the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(2) Limitations

Infant formula may be imported pursuant to paragraph (1) only if the infant formula—

(A) is exclusively for personal use and will not be commercialized or promoted; and

(B) does not present an unreasonable risk to human health.

(3) Reporting of adverse events

If a health care provider becomes aware of any adverse event which the health care provider reasonably suspects to be associated with infant formula imported pursuant to paragraph (1), the health care provider shall report such adverse event to the Commissioner of Food and Drugs.

(4) Public notice

The Secretary, acting through the Commissioner of Food and Drugs, shall post on the public website of the Food and Drug Administration notice that—

(A) infant formula imported pursuant to paragraph (1) may not have been manufactured in a facility that has been inspected by the Food and Drug Administration;

(B) the labeling of such infant formula may not meet the standards and other requirements applicable with respect to infant formula under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(C) the nutritional content of infant formula imported pursuant to paragraph (1) may vary from that of infant formula meeting such standards and other requirements.

(5) Sense of Congress

It is the sense of Congress that persons considering the personal importation of infant formula should consult with their pediatrician about such importation.

(Pub. L. 117–328, div. FF, title III, § 3401, Dec. 29, 2022, 136 Stat. 5838.)

Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (m)(1), (4)(B), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§ 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

CODIFICATION

Section was enacted as part of the Food and Drug Omnibus Reform Act of 2022, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

Section is comprised of section 3401 of div. FF of Pub. L. 117–328. Subsec. (a)(2) of section 3401 of div. FF of Pub. L. 117–328 amended section 321 of this title. Subsecs. (c), (g)(1)–(4), (6), and (*l*) of such section 3401 amended section 350a of this title. Subsec. (k) of such section 3401 enacted section 350m of this title.

Statutory Notes and Related Subsidiaries

DEFINITION OF ''SECRETARY''

Pub. L. 117–328, div. FF, title III, § 3002, Dec. 29, 2022, 136 Stat. 5807, provided that: ''In this title [see Short Title of 2022 Amendment note set out under section 301 of this title], except as otherwise specified, the term 'Secretary' means the Secretary of Health and Human Services.''

§ 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 pre-

scribing 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 Administration 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.

(June 25, 1938, ch. 675, § 413, as added Pub. L. 103–417, § 8, Oct. 25, 1994, 108 Stat. 4331; amended Pub. L. 111–353, title I, § 113(a), Jan. 4, 2011, 124 Stat. 3920.)

Editorial Notes

AMENDMENTS

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

Statutory Notes and Related Subsidiaries

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, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article, and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

(2) Use of or exposure to food of concern

If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause 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, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.

(3) Application

The requirement under paragraphs (1) and (2) applies to all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.