

2007, 121 Stat. 962, which enacted this chapter and section 350f of this title, amended sections 321 and 331 of this title, and enacted provisions set out as notes under this section and section 350f of this title. For complete classification of title X to the Code, see Tables.

The Dietary Supplement Health and Education Act of 1994, referred to in par. (1), is Pub. L. 103-417, Oct. 25, 1994, 108 Stat. 4325, which enacted sections 343-2 and 350b of this title and section 287c-11 of Title 42, The Public Health and Welfare, amended sections 321, 331, 342, 343, and 350 of this title and section 281 of Title 42, and enacted provisions set out as notes under sections 321 and 343 of this title. For complete classification of this Act to the Code, see Short Title of 1994 Amendments note set out under section 301 of this title and Tables.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act, referred to in par. (2), is Pub. L. 109-462, Dec. 22, 2006, 120 Stat. 3469, which enacted sections 379aa and 379aa-1 of this title, amended sections 331, 343, 352, and 381 of this title, and enacted provisions set out as notes under sections 331, 343, 352, 379aa, and 381 of this title. For complete classification of this Act to the Code, see Short Title of 2006 Amendment note set out under section 301 of this title and Tables.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Pub. L. 110-85, title X, §1005(g), Sept. 27, 2007, 121 Stat. 969, provided that: “Nothing in this title [enacting this chapter and section 350f of this title, amending sections 321 and 331 of this title, and enacting provisions set out as notes under section 350f of this title], or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations.”

CHAPTER 27—FOOD SAFETY MODERNIZATION

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SUBCHAPTER I—IMPROVING CAPACITY TO PREVENT FOOD SAFETY PROBLEMS

§ 2201. Performance standards

(a) In general

The Secretary shall, in coordination with the Secretary of Agriculture, not less frequently than every 2 years, review and evaluate relevant health data and other relevant information, including from toxicological and epidemiological studies and analyses, current Good Manufacturing Practices issued by the Secretary relating to food, and relevant recommendations of relevant advisory committees, including the Food Advisory Committee, to determine the most significant foodborne contaminants.

(b) Guidance documents and regulations

Based on the review and evaluation conducted under subsection (a), and when appropriate to reduce the risk of serious illness or death to humans or animals or to prevent adulteration of the food under section 342 of this title or to prevent the spread by food of communicable disease under section 264 of title 42, the Secretary shall issue contaminant-specific and science-based guidance documents, including guidance documents regarding action levels, or regulations. Such guidance, including guidance regarding action levels, or regulations—

(1) shall apply to products or product classes;

(2) shall, where appropriate, differentiate between food for human consumption and food intended for consumption by animals other than humans; and

(3) shall not be written to be facility-specific.

(c) No duplication of efforts

The Secretary shall coordinate with the Secretary of Agriculture to avoid issuing duplicative guidance on the same contaminants.

(d) Review

The Secretary shall periodically review and revise, as appropriate, the guidance documents, including guidance documents regarding action levels, or regulations promulgated under this section.

(Pub. L. 111-353, title I, §104, Jan. 4, 2011, 124 Stat. 3899.)

Editorial Notes

REFERENCES IN TEXT

The Secretary, referred to in text, probably means the Secretary of Health and Human Services.

Statutory Notes and Related Subsidiaries

SHORT TITLE

Pub. L. 111-353, §1(a), Jan. 4, 2011, 124 Stat. 3885, provided that: “This Act [enacting this chapter and sections 350g to 350l-1, 379j-31, 384a to 384d, 399c, and 399d of this title, section 7625 of Title 7, Agriculture, and section 280g-16 of Title 42, The Public Health and Welfare, amending sections 331, 333, 334, 350b to 350d, 350f, 374, 381, 393, and 399 of this title and section 247b-20 of Title 42, and enacting provisions set out as notes under sections 331, 334, 342, 350b, 350d, 350e, 350g to 350j, 350l, and 381 of this title] may be cited as the ‘FDA Food Safety Modernization Act’.”