

industry, the Secretary shall hold discussions with representatives of veterinary, patient, and consumer advocacy groups to continue discussions of their views on the reauthorization and their suggestions for changes to this subpart as expressed under paragraph (2).

**(4) Public review of recommendations**

After negotiations with the regulated industry, the Secretary shall—

(A) present the recommendations developed under paragraph (1) to the congressional committees specified in such paragraph;

(B) publish such recommendations in the Federal Register;

(C) provide for a period of 30 days for the public to provide written comments on such recommendations;

(D) hold a meeting at which the public may present its views on such recommendations; and

(E) after consideration of such public views and comments, revise such recommendations as necessary.

**(5) Transmittal of recommendations**

Not later than January 15, 2013, the Secretary shall transmit to Congress the revised recommendations under paragraph (4), a summary of the views and comments received under such paragraph, and any changes made to the recommendations in response to such views and comments.

**(6) Minutes of negotiation meetings**

**(A) Public availability**

Before presenting the recommendations developed under paragraphs (1) through (5) to Congress, the Secretary shall make publicly available, on the Internet Web site of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between the Food and Drug Administration and the regulated industry.

**(B) Content**

The minutes described under subparagraph (A) shall summarize any substantive proposal made by any party to the negotiations as well as significant controversies or differences of opinion during the negotiations and their resolution.

(June 25, 1938, ch. 675, §742, as added Pub. L. 110-316, title II, §203, Aug. 14, 2008, 122 Stat. 3522.)

TERMINATION OF SECTION

*For termination of section by section 204(b) of Pub. L. 110-316, see Termination Date note below.*

REFERENCES IN TEXT

Section 201(3) of the Animal Generic Drug User Fee Act of 2008, referred to in subsec. (a), probably means section 201(b)(3) of Pub. L. 110-316, which is set out as a note under section 379j-21 of this title.

PRIOR PROVISIONS

A prior section 742 of act June 25, 1938, was renumbered section 746 and is classified to section 379l of this title.

TERMINATION DATE

Pub. L. 110-316, title II, §204(b), Aug. 14, 2008, 122 Stat. 3524, provided that: “The amendment made by section

203 [enacting this section] shall cease to be effective January 31, 2014.”

PART D—INFORMATION AND EDUCATION

**§ 379k. Information system**

The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.

(June 25, 1938, ch. 675, §745, formerly §741, as added Pub. L. 105-115, title IV, §407(a), Nov. 21, 1997, 111 Stat. 2370; renumbered §745, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

AMENDMENT OF SECTION

*For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.*

TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out as a Termination Date note under section 379j-21 of this title.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

REPORT ON STATUS OF SYSTEM

Section 407(b) of Pub. L. 105-115 provided that not later than 1 year after Nov. 21, 1997, Secretary of Health and Human Services was to submit report to Congress on status of system to be established under this section, including projected costs of system and concerns about confidentiality.

**§ 379l. Education**

**(a) In general**

The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this chapter, including programs for—

(1) scientific training;

(2) training to improve the skill of officers and employees authorized to conduct inspections under section 374 of this title;

(3) training to achieve product specialization in such inspections; and

(4) training in administrative process and procedure and integrity issues.

**(b) Intramural fellowships and other training programs**

The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians. Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary deter-

mines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.

(June 25, 1938, ch. 675, §746, formerly §742, as added Pub. L. 105-115, title IV, §408(a), Nov. 21, 1997, 111 Stat. 2371; amended Pub. L. 110-85, title VI, §601(c), Sept. 27, 2007, 121 Stat. 897; renumbered §746, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

#### AMENDMENT OF SECTION

*For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.*

#### PRIOR PROVISIONS

A prior section 746 of act June 25, 1938, was renumbered section 749 and is classified to section 379o of this title.

#### AMENDMENTS

2007—Subsec. (b). Pub. L. 110-85 inserted at end “Any such fellowships and training programs under this section or under section 379dd(d)(2)(A)(ix) of this title may include provision by such scientists and physicians of services on a voluntary and uncompensated basis, as the Secretary determines appropriate. Such scientists and physicians shall be subject to all legal and ethical requirements otherwise applicable to officers or employees of the Department of Health and Human Services.”

#### TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out as a Termination Date note under section 379j-21 of this title.

#### EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

#### PART E—ENVIRONMENTAL IMPACT REVIEW

### § 379o. Environmental impact

Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this chapter, shall be considered to meet the requirements for a detailed statement under section 4332(2)(C) of title 42.

(June 25, 1938, ch. 675, §749, formerly §746, as added Pub. L. 105-115, title IV, §411, Nov. 21, 1997, 111 Stat. 2373; renumbered §749, Pub. L. 110-316, title II, §202(a), Aug. 14, 2008, 122 Stat. 3515.)

#### AMENDMENT OF SECTION

*For termination of amendment renumbering this section by section 204(a) of Pub. L. 110-316, see Termination Date of 2008 Amendment note below.*

#### TERMINATION DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110-316 to cease to be effective Oct. 1, 2013, see section 204(a) of Pub. L. 110-316, set out

as a Termination Date note under section 379j-21 of this title.

#### EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

#### PART F—NATIONAL UNIFORMITY FOR NON-PRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

### § 379r. National uniformity for nonprescription drugs

#### (a) In general

Except as provided in subsection (b), (c)(1), (d), (e), or (f) of this section, no State or political subdivision of a State may establish or continue in effect any requirement—

(1) that relates to the regulation of a drug that is not subject to the requirements of section 353(b)(1) or 353(f)(1)(A) of this title; and

(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

#### (b) Exemption

##### (1) In general

Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

(C) would not unduly burden interstate commerce.

##### (2) Timely action

The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

#### (c) Scope

##### (1) In general

This section shall not apply to—

(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

##### (2) Safety or effectiveness

For purposes of subsection (a) of this section, a requirement that relates to the regulation of a drug shall be deemed to include any