market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, § 2127, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, § 4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, § 6601(q), Dec. 19, 1989, 103 Stat. 2292.)

Editorial Notes

CODIFICATION

In subsecs. (a)(1), (c), ''December 22, 1987'' substituted for ''the effective date of this subpart'' on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).

1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted ''effective date of this subpart'' for ''effective date of this part''.

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§ 300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or con-

cealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, § 2128, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, § 4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

CODIFICATION

In subsec. (a), ''December 22, 1987'' substituted for ''the effective date of this subpart'' on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

AMENDMENTS

1987—Subsec. (a). Pub. L. 100–203 substituted ''effective date of this subpart'' for ''effective date of this part''.

SUBPART D—GENERAL PROVISIONS

§ 300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, § 2131, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, § 4305, Dec. 22, 1987, 101 Stat. 1330–224.)

Editorial Notes

AMENDMENTS

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting ''to any plaintiff who substantially prevails on one or more significant issues in the action'' for ''to any party, whenever the court determines that such award is appropriate'', was executed by making the substitution for ''to any party, whenever the court determines such award is appropriate'', to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§ 300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, § 2132, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778.)

§ 300aa–33. Definitions

For purposes of this part:

(1) The term ''health care provider'' means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term ''legal representative'' means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term ''manufacturer'' means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term ''manufacture'' means to manufacture, import, process, or distribute a vaccine.

(4) The term ''significant aggravation'' means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term ''vaccine-related injury or death'' means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term ''Advisory Commission on Childhood Vaccines'' means the Commission established under section 300aa–19 of this title.

(B) The term ''Vaccine Injury Table'' means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, § 2133, as added Pub. L. 99–660, title III, § 311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§ 1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, § 102(a), Feb. 20, 2003, 117 Stat. 528.)

Editorial Notes

AMENDMENTS

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§ 1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, § 1714, which directed amendment of first sentence by substituting ''any vac-