§ 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 concealed 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.)

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.)

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.

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.)

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 vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine'' for ''under its label any vaccine set forth in the Vaccine Injury Table'' and of second sentence by inserting ''including any component or ingredient of any such vaccine'' before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, § 1715, which directed insertion of ''For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label.'' at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, § 1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, § 102(a). Par. (7) read as follows: ''The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label.''

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–296, title XVII, § 1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, § 102(a), Feb. 20, 2003, 117 Stat. 528.

CONSTRUCTION OF AMENDMENTS

Pub. L. 108–7, div. L, § 102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

''(b) APPLICATION OF THE PUBLIC HEALTH SERVICE ACT.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

''(c) RULE OF CONSTRUCTION.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided.''

§ 300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows: