

### § 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.