Pub. L. 109–462, § 3(d)(3), Dec. 22, 2006, 120 Stat. 3475, enacted provisions substantially identical to those enacted by Pub. L. 109–462, § 2(b), set out above.

§ 379aa–1. Serious adverse event reporting for dietary supplements

(a) Definitions

In this section:

(1) Adverse event

The term ''adverse event'' means any health-related event associated with the use of a dietary supplement that is adverse.

(2) Serious adverse event

The term ''serious adverse event'' is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(3) Serious adverse event report

The term ''serious adverse event report'' means a report that is required to be submitted to the Secretary under subsection (b).

(b) Reporting requirement

(1) In general

The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 343(e)(1) of this title) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the ''responsible person'') shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.

(2) Retailer

A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 343(y) of this title.

(c) Submission of reports

(1) Timing of reports

The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 343(y) of this title.

(2) New medical information

The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

(3) Consolidation of reports

The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) Exemption

The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

(d) Contents of reports

Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

(e) Maintenance and inspection of records

(1) Maintenance

The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) Records inspection

(A) In general

The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 374 of this title.

(B) Authorized person

For purposes of this paragraph, the term ''authorized person'' means an officer or employee of the Department of Health and Human Services, who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) Protected information

A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 379v of this title and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5 (commonly referred to as the ''Privacy Act of 1974'') and a medical or similar file the disclosure of which would con-

stitute a violation of section 552 of such title 5 (commonly referred to as the ''Freedom of Information Act''), and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) Rule of construction

The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

(h) Preemption

(1) In general

No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this section.

(2) Effect of section

(A) In general

Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(B) Personally-identifiable information

Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(C) Use of safety reports

Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 379v of this title.

(i) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary.

(June 25, 1938, ch. 675, § 761, as added Pub. L. 109–462, § 3(a), Dec. 22, 2006, 120 Stat. 3472.)

EFFECTIVE DATE

Section effective 1 year after Dec. 22, 2006, see section 3(d)(1) of Pub. L. 109–462, set out as an Effective Date of 2006 Amendment note under section 343 of this title.

PART I—REAGAN-UDALL FOUNDATION FOR THE FOOD AND DRUG ADMINISTRATION

§ 379dd. Establishment and functions of the Foundation

(a) In general

A nonprofit corporation to be known as the Reagan-Udall Foundation for the Food and Drug Administration (referred to in this part as the ''Foundation'') shall be established in accordance with this section. The Foundation shall be headed by an Executive Director, appointed by the members of the Board of Directors under subsection (e).[1] The Foundation shall not be an agency or instrumentality of the United States Government.

(b) Purpose of Foundation

The purpose of the Foundation is to advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.

(c) Duties of the Foundation

The Foundation shall—

(1) taking into consideration the Critical Path reports and priorities published by the Food and Drug Administration, identify unmet needs in the development, manufacture, and evaluation of the safety and effectiveness, including postapproval, of devices, including diagnostics, biologics, and drugs, and the safety of food, food ingredients, and cosmetics, and including the incorporation of more sensitive and predictive tools and devices to measure safety;

(2) establish goals and priorities in order to meet the unmet needs identified in paragraph (1);

(3) in consultation with the Secretary, identify existing and proposed Federal intramural and extramural research and development programs relating to the goals and priorities established under paragraph (2), coordinate Foundation activities with such programs, and minimize Foundation duplication of existing efforts;

(4) award grants to, or enter into contracts, memoranda of understanding, or cooperative agreements with, scientists and entities, which may include the Food and Drug Administration, university consortia, public-private partnerships, institutions of higher education, entities described in section 501(c)(3) of title 26 (and exempt from tax under section 501(a) of such title), and industry, to efficiently and effectively advance the goals and priorities established under paragraph (2);

(5) recruit meeting participants and hold or sponsor (in whole or in part) meetings as appropriate to further the goals and priorities established under paragraph (2);

(6) release and publish information and data and, to the extent practicable, license, distribute, and release material, reagents, and techniques to maximize, promote, and coordinate the availability of such material, reagents,

[1] So in original. Probably should be ''subsection (g).''