**SEC. 761.** [21 USC § 379aa-1] Serious adverse event reporting for dietary supplements [Caution: This section is effective 1 year after enactment, pursuant to § 3(d)(1) of Act Dec. 22, 2006, P.L. 109-462]

(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 403(e)(1) [21 USC § 343(e)(1)]) 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 403(y) [21 USC § 343(y)].

(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 403(y) [21 USC § 343(y)].
(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 704 [21 USC § 374].
(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 756 [21 USC § 379v] 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, United States Code [5 USC § 552a] (commonly referred to as the "Privacy Act of 1974") and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 [5 USC § 552] (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 756 [21 USC § 379v].

(i) Authorization of appropriations. There are authorized to be appropriated to carry out this section such sums as may be necessary.