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109TH CONGRESS
2D SESSION

H. R. 6168

To amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2006

Mr. CANNON introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Dietary Supplement and Nonprescription Drug Consumer Protection Act''.

SEC. 2. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"Subchapter H—Serious Adverse Event Reports

"SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NONPRESCRIPTION DRUGS.

"(a) DEFINITIONS.—In this section:

"(1) ADVERSE EVENT.—The term 'adverse event' means any health-related event associated with the use of a nonprescription drug that is adverse, including—

"(A) an event occurring from an overdose of the drug, whether accidental or intentional;

"(B) an event occurring from abuse of the drug;

"(C) an event occurring from withdrawal from the drug; and

"(D) any failure of expected pharmacological action of the drug.

"(2) NONPRESCRIPTION DRUG.—The term 'nonprescription drug' means a drug that is—

"(A) not subject to section 503(b); and

''(B) not subject to approval in an application submitted under section 505.

''(3) 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).

''(4) 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 whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug 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 drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

''(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 nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such drug that are reported to the retailer through the address or telephone number described in section 502(x).

''(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 502(x).

''(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 re-

sponsible 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 nonprescription drugs, 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.

''(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 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 con-

stitute 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 (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 (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 nonprescription drug 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 nonprescription drugs, 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 Sec-

retary in a manner inconsistent with subsection (g) or section 756.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

(b) MODIFICATIONS.—The Secretary of Health and Human Services may modify requirements under the amendments made by this section in accordance with section 553 of title 5, United States Code, to maintain consistency with international harmonization efforts over time.

(c) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking '', or 704(a);'' and inserting '', 704(a), or 760;''; and

(2) striking '', or 564'' and inserting '', 564, or 760''.

(d) MISBRANDING.—Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is amended by adding at the end the following:

''(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible per-

son (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.''.

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 502(x) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any nonprescription drug (as defined in such section 502(x)) labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report described under the amendments made by this Act.

SEC. 3. SERIOUS ADVERSE EVENT REPORTING FOR DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

"SEC. 761. 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 403(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).

''(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).

''(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.

''(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 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 (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 (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 con-

sent 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.

''(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.''.

(b) PROHIBITED ACT.—Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(e)) is amended by—

(1) striking '', or 760;'' and inserting '', 760, or 761;''; and

(2) striking '', or 760'' and inserting '', 760, or 761''.

(c) MISBRANDING.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as de-

scribed in section 761) may receive a report of a serious adverse event with such dietary supplement.''.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall take effect 1 year after the date of enactment of this Act.

(2) MISBRANDING.—Section 403(y) of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall apply to any dietary supplement labeled on or after the date that is 1 year after the date of enactment of this Act.

(3) GUIDANCE.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance on the minimum data elements that should be included in a serious adverse event report as described under the amendments made by this Act.

SEC. 4. PROHIBITION OF FALSIFICATION OF REPORTS.

(a) IN GENERAL.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse

event report (as defined under section 760 or 761) submitted to the Secretary.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect 1 year after the date of enactment of this Act.

SEC. 5. IMPORTATION OF CERTAIN NONPRESCRIPTION DRUGS AND DIETARY SUPPLEMENTS.

(a) IN GENERAL.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a), by inserting after the third sentence the following: ''If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section.''; and

(2) in the second sentence of subsection (b)—

(A) by inserting ''(1)'' before ''an article included'';

(B) by inserting before ''final determination'' the following: ''or (2) with respect to an

article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be,''; and

(C) by inserting '', or, with respect to clause (2), the responsible person,'' before ''to perform''.

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act.

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