AMENDMENT TO THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4421

OFFERED BY M__. _____

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Page 26, after line 12, add the following:

SEC. 114. ENHANCED DRUG MANUFACTURING AMOUNT INFORMATION REPORTING.

(a) IN GENERAL.—

(1) REPORT REQUIRED.—If the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') determines that it would support public health security and all-hazards preparedness and response for emergency periods (as defined in section 1135(g)(1) of the Social Security Act (42 U.S.C. 1320b-5(g)(1))), the Secretary may issue a regulation requiring every person who owns or operates any establishment in any State or foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs for sale or import into the United States shall report to the Secretary information described in subsection (b) in such manner as the Secretary shall specify in regulation or guidance.

(2) TIMING OF REPORT.—Reports shall be submitted pursuant to paragraph (1) more frequently than annually, in accordance with a reporting schedule as may be specified by the Secretary in regulation or guidance, but not more frequently than 4 times per year.

(3) OTHER REPORTS.—The Secretary may require information described in subsection (b) to be included in reports to the Secretary otherwise required by law.

(4) CONFIDENTIAL INFORMATION.—Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret or confidential information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code.

(b) INCLUSIONS.—Reports required pursuant to regulations under subsection (a) shall include—

(1) the identity of the respective suppliers of each active pharmaceutical ingredient, active pharmaceutical ingredient intermediate, and in-process material used in such manufacture, preparation, propagation, compounding, or processing of a drug manufactured, prepared, propagated, compounded or processed at the establishment; and

(2) the respective amounts of such drug that were manufactured, prepared, propagated, compounded, or processed using an active pharmaceutical ingredient, active pharmaceutical ingredient intermediate, and in-process material from each such identified supplier.

(c) DRUG DEFINED.—In this section, the term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

SEC. 115. REQUIRE DRUG LABELING TO INCLUDE ORIGINAL MANUFACTURE AND SUPPLY CHAIN INFORMATION.

(a) IN GENERAL.—If the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') determines that it would support public health security and all-hazards preparedness and response for emergency periods (as defined in section 1135(g)(1) of the Social Security Act (42 U.S.C. 1320b-5(g)(1))), the Secretary may issue a regulation to require that drugs, including active pharmaceutical ingredients, bear a label containing the name and place of business, and unique facility identifier of the original manufacturer of such drug or active pharmaceutical ingredient.

(b) MISBRANDING.—The Secretary may deem a drug that does not comply with the regulation issued under subsection (a) as misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352).

(c) DRUG DEFINED.—In this section, the term ''drug'' has the meaning given such term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301).

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