HR 1483

Drug Safety Enhancement Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Introduced: Apr 12, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 15, 2011)
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Sponsor

Name: Rep. Dingell, John D. [D-MI-15]
Party: Democratic • **State:** MI • **Chamber:** House

Cosponsors (15 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeGette, Diana [D-CO-1]	D · CO		Apr 12, 2011
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		Apr 12, 2011
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Apr 12, 2011
Rep. Capps, Lois [D-CA-23]	D · CA		Apr 14, 2011
Rep. Clarke, Hansen [D-MI-13]	D · MI		Apr 14, 2011
Rep. McGovern, James P. [D-MA-3]	D · MA		Apr 14, 2011
Rep. Slaughter, Louise McIntosh [D-NY-28]	D · NY		May 2, 2011
Rep. Stark, Fortney Pete [D-CA-13]	D · CA		May 5, 2011
Rep. Speier, Jackie [D-CA-12]	D · CA		Jul 7, 2011
Rep. Jackson, Jesse L., Jr. [D-IL-2]	D · IL		Sep 7, 2011
Rep. Rush, Bobby L. [D-IL-1]	D · IL		Sep 7, 2011
Rep. Ackerman, Gary L. [D-NY-5]	D · NY		Feb 1, 2012
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		Feb 17, 2012
Rep. Lee, Barbara [D-CA-9]	D · CA		Mar 5, 2012
Rep. Kaptur, Marcy [D-OH-9]	D · OH		Mar 22, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 15, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 12, 2011)

Drug Safety Enhancement Act of 2011 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to expand drug establishment registration requirements to include foreign drug establishments and establishments manufacturing, preparing, propagating, compounding, or processing excipients of drugs (i.e., inactive drug additives). Requires the Secretary of Health and Human Services (HHS) to collect registration fees.

Requires drug manufacturers to: (1) implement an effective quality system that requires compliance with current good manufacturing practices and timely communication of product quality issues; (2) establish risk management procedures that ensure effective risk assessment, control, and communication; and (3) establish procedures that ensure the safety, identity, quality, strength, purity, and security of all drugs and other materials used by the manufacturer.

Requires drug establishments to maintain records on the supply chain of the drug, ingredients, and raw materials.

Establishes the frequency of inspections of drug establishments. Prohibits delaying or limiting an inspection.

Gives the Secretary authority to order the recall of, detain, destroy, and seize drugs as necessary.

Establishes civil and criminal penalties for violations of FFDCA provisions.

Authorizes the Secretary to require documentation of an imported drug and refuse admission if such documentation is not provided.

Requires the Secretary to: (1) require drug importers to register and to comply with good importer practices, (2) require a customs broker with respect to drugs to register, and (3) establish a corps of inspectors dedicated to inspections of foreign drug facilities and establishments.

Requires drug establishments, importers, and customs brokers to have a unique identifier.

Deems a finished dosage form drug to be misbranded if the manufacturer's website does not list country of origin labeling for each active pharmaceutical ingredient and the place of manufacture of the finished dosage form of such drug.

Gives the Commissioner of the Food and Drug Administration (FDA) subpoena authority.

Establishes whistleblower protections.

Actions Timeline

- **Apr 15, 2011:** Referred to the Subcommittee on Health.
- **Apr 12, 2011:** Introduced in House
- **Apr 12, 2011:** Referred to the House Committee on Energy and Commerce.

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