S 3409

Drug and Device Accountability Act of 2008

Congress: 110 (2007–2009, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Jul 31, 2008
Current Status: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
Latest Action: Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Jul 31, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/senate-bill/3409

Sponsor

Name: Sen. Kennedy, Edward M. [D-MA]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Grassley, Chuck [R-IA]	R · IA		Jul 31, 2008

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Aug 1, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Jul 31, 2008)

Drug and Device Accountability Act of 2008 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to deem a drug or device to be misbranded unless certain conditions related to registration of establishments, identification of prior transactions, labeling for country of manufacture, and provision of required information on importation are met.

Includes in the definition of "drug" a precursor ingredient.

Repeals the registration exemption for manufacturers of harmless inactive ingredients that become components of drugs.

Expands the information required to be included for registration of establishments.

Deems a drug to be adulterated if certain conditions related to verification of identity and purity, identification of establishments, consistency with current manufacturing technologies, and conformity with good distribution and import practices are not met.

Sets forth provisions governing importation of a drug.

Sets forth required actions, including cessation of distribution, if there is a reasonable probability that a drug intended for human use would cause serious, adverse health consequences or death.

Establishes actions manufacturers must take regarding any defective drug.

Sets forth additional required certifications for submissions related to drugs and devices regarding accuracy of information submitted and personal knowledge of such information.

Establishes whistleblower protection for employees providing information regarding a drug, biological product, or device.

Directs the Secretary of Health and Human Services to establish and maintain a corps of inspectors dedicated to inspections of foreign establishments and foreign facilities.

Authorizes the Secretary to conduct investigations, subpoena witnesses, and compel attendance of witnesses as necessary to carry out authority under the FFDCA or provisions governing the regulation of biological products.

Requires reports to the Secretary regarding certain civil actions involving a regulated product.

Actions Timeline

- **Jul 31, 2008:** Introduced in Senate
- **Jul 31, 2008:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.