S 882

Drug and Device Accountability Act of 2009

Congress: 111 (2009–2011, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 23, 2009
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. (Apr 23, 2009)
Official Text: https://www.congress.gov/bill/111th-congress/senate-bill/882

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		Apr 23, 2009

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 23, 2009

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 23, 2009)

Drug and Device Accountability Act of 2009 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to revise provisions regarding the registration of drug and device establishments, including to: (1) expand the information required to be included in a registration; and (2) provide for risk-based inspections.

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

Requires the Secretary of Health and Human Services (HHS) to assess the registration exemption for manufacturers of harmless inactive ingredients that become components of drugs.

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.

Deems a drug or device to be misbranded unless certain conditions related to labeling for country of manufacture and provision of required information on importation are met.

Sets forth provisions governing importation of a drug and its components.

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 and personal knowledge of information submitted.

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

Requires the Secretary to contract with the Institute of Medicine to evaluate: (1) the organizational structure and operations of the Food and Drug Administration (FDA) with respect to the review of medical devices for clearance and for premarket approval under FFDCA; and (2) the analytical and methodological tools used to conduct such reviews.

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

Sets forth enforcement provisions.

Actions Timeline

- **Apr 23, 2009:** Introduced in Senate
- **Apr 23, 2009:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.