HR 2273

Food and Drug Administration Improvement Act of 2007

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: May 10, 2007
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 10, 2007)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/2273

Sponsor

Name: Rep. Hinchey, Maurice D. [D-NY-22]
Party: Democratic • **State:** NY • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Grijalva, Raúl M. [D-AZ-7]	D · AZ		May 10, 2007
Rep. Stupak, Bart [D-MI-1]	D · MI		May 10, 2007

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 10, 2007

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 10, 2007)

Food and Drug Administration Improvement Act of 2007 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require that all fees collected for the review of applications for human drugs, devices, and animal drugs be deposited in the general fund of the Treasury. Makes available amounts necessary for the Secretary of Health and Human Services to review such applications.

Prohibits the Secretary from entering into agreements with persons from whom such fees are collected and terminates any existing agreements.

Requires the Secretary to: (1) establish the Center for Postmarket Drug Safety and Effectiveness within the Food and Drug Administration (FDA) to regulate approved drugs; and (2) transfer to the Center all responsibilities for such regulation from the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research.

Allows the Secretary to require manufacturers of approved drugs to conduct studies of an identified significant safety issue with the drug.

Deems a drug to be misbranded if it does not meet the Secretary's requirements, including requirements for labeling and conducting postmarket studies.

Requires the Secretary to follow the interpretation that the FDA used in 1999 that the FFDCA and Public Health Service Act establish minimal standards but do not preclude additional state requirements. Requires the Secretary to cease intervening in product liability civil actions to argue another interpretation.

Sets forth procedures for advisory committee meetings to ensure that the committee is fairly balanced. Prohibits any exemptions from being granted to advisory committee members from rules prohibiting members from having a personal financial interest in the outcome.

Requires doctors to inform patients and obtain consent to prescribe an approved drug for a purpose that has not been approved by the FDA.

Actions Timeline

- **May 10, 2007:** Introduced in House
- **May 10, 2007:** Referred to the House Committee on Energy and Commerce.
- **May 10, 2007:** Referred to the Subcommittee on Health.