# HR 4816

Food and Drug Administration Improvement Act of 2010

**Congress:** 111 (2009–2011, Ended)
**Chamber:** House
**Policy Area:** Health
**Introduced:** Mar 10, 2010
**Current Status:** Referred to the House Committee on Energy and Commerce.
**Latest Action:** Referred to the House Committee on Energy and Commerce. (Mar 10, 2010)
**Official Text:** https://www.congress.gov/bill/111th-congress/house-bill/4816

## Sponsor

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

## Cosponsors

*No cosponsors are listed for this bill.*

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Energy and Commerce Committee | House | Referred To | Mar 10, 2010 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

*No related bills are listed.*

## Summary (as of Mar 10, 2010)

Food and Drug Administration Improvement Act of 2010 - Amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require that all fees collected for the review of applications for human drugs, devices, animal drugs, or generic animal drugs be deposited in the general fund of the Treasury. Makes available amounts necessary for the Secretary of Health and Human Services (HHS) 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, Device, and Biologic 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, the Center for Biologics Evaluation and Research, or the Center for Devices and Radiological Health Organization.

Requires a statement regarding the reporting of negative side effects of prescription drugs in televised direct-to-consumer drug advertisements (currently required in published advertisements).

Requires the Commissioner of Food and Drugs to: (1) complete a review of the FDA's regulations and guidance pertaining to the labeling of drugs and biological products; and (2) post on the FDA's website all clinical trial adverse events included in the registry and results data bank of the National Institutes of Health (NIH).

Requires payment of a fee to the Secretary for the advertisement of drugs and devices.

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

- **Mar 10, 2010:** Introduced in House
- **Mar 10, 2010:** Referred to the House Committee on Energy and Commerce.