

HR 6483

Improved Transparency of Foreign Drug Manufacturing Act of 2022

Congress: 117 (2021–2023, Ended)

Chamber: House

Policy Area: Health

Introduced: Jan 25, 2022

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jan 26, 2022)

Official Text: <https://www.congress.gov/bill/117th-congress/house-bill/6483>

Sponsor

Name: Rep. Eshoo, Anna G. [D-CA-18]

Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jan 26, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
117 S 1366	Related bill	Apr 26, 2021: Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Improved Transparency of Foreign Drug Manufacturing Act of 2022

This bill modifies requirements for certain foreign establishments that manufacture drugs (including active pharmaceutical ingredients) to register with the Food and Drug Administration (FDA).

Under this bill, if an establishment outside of the United States manufactures (or otherwise processes or prepares) a drug to be imported (or offered for import) into the United States, the establishment must comply with the registration requirements even if the drug undergoes further manufacturing at another non-U.S. establishment prior to importation into the United States.

A non-U.S. manufacturing establishment must also file with the FDA a list of drugs manufactured by the establishment. For each drug on the list, the establishment must (1) identify every other known establishment where additional manufacturing is performed, and (2) notify each foreign establishment involved of the listing of the drug and the obligation to register with the FDA.

The bill also requires each registered non-U.S. manufacturing establishment to report every three months to the FDA a list of each drug it manufactures for commercial distribution, where currently this report is required once a year.

Actions Timeline

- **Jan 26, 2022:** Referred to the Subcommittee on Health.
- **Jan 25, 2022:** Introduced in House
- **Jan 25, 2022:** Referred to the House Committee on Energy and Commerce.

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