

S 3509

Creating Efficiency in Foreign Facility Inspections Act

Congress: 117 (2021–2023, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Jan 13, 2022

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. (Jan 13, 2022)

Official Text: <https://www.congress.gov/bill/117th-congress/senate-bill/3509>

Sponsor

Name: Sen. Braun, Mike [R-IN]

Party: Republican • **State:** IN • **Chamber:** Senate

Cosponsors (2 total)

| Cosponsor | Party / State | Role | Date Joined |
|--------------------------|---------------|------|--------------|
| Sen. Ernst, Joni [R-IA] | R · IA | | Jan 13, 2022 |
| Sen. Hawley, Josh [R-MO] | R · MO | | Jan 19, 2022 |

Committee Activity

| Committee | Chamber | Activity | Date |
|--|---------|-------------|--------------|
| Health, Education, Labor, and Pensions Committee | Senate | Referred To | Jan 13, 2022 |

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Creating Efficiency in Foreign Facility Inspections Act

This bill prohibits, with some exceptions, the Food and Drug Administration (FDA) from providing notification in advance of a planned inspection of an establishment located outside of the United States that is engaged in drug manufacturing, processing, packing, or holding.

Specifically, the FDA may not provide such an establishment advance notification of a planned inspection unless (1) advance notification is required by the laws of the country where the establishment is located; (2) providing advance notification is needed to protect the public health; or (3) the inspection in question is a preapproval, prelicensure, or for-cause inspection. If the FDA must provide advance notification, it must minimize the time between the notification and the inspection.

If an establishment is located in a country that, on or after the date this bill is enacted, enacts a law requiring advance notification of inspections, the drug manufacturer must agree to waive the right to enforce the requirement, to the extent expressly permitted by the law.

Actions Timeline

- **Jan 13, 2022:** Introduced in Senate
- **Jan 13, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.