# HR 1736

To amend the Federal Food, Drug, and Cosmetic Act to improve the process for inspections of device establishments and for granting export certifications.

**Congress:** 115 (2017–2019, Ended)
**Chamber:** House
**Policy Area:** Health
**Introduced:** Mar 27, 2017
**Current Status:** Referred to the Subcommittee on Health.
**Latest Action:** Referred to the Subcommittee on Health. (Mar 31, 2017)
**Official Text:** https://www.congress.gov/bill/115th-congress/house-bill/1736

## Sponsor

**Name:** Rep. Bucshon, Larry [R-IN-8]
**Party:** Republican • **State:** IN • **Chamber:** House

## Cosponsors (8 total)

| Cosponsor | Party / State | Role | Date Joined |
|---|---|---|---|
| Rep. Brooks, Susan W. [R-IN-5] | R · IN | | Mar 27, 2017 |
| Rep. Butterfield, G. K. [D-NC-1] | D · NC | | Mar 27, 2017 |
| Rep. Peters, Scott H. [D-CA-52] | D · CA | | Mar 27, 2017 |
| Rep. Blackburn, Marsha [R-TN-7] | R · TN | | Apr 14, 2017 |
| Rep. Banks, Jim [R-IN-3] | R · IN | | Apr 25, 2017 |
| Rep. Hudson, Richard [R-NC-8] | R · NC | | Apr 27, 2017 |
| Rep. Gottheimer, Josh [D-NJ-5] | D · NJ | | Jun 21, 2017 |
| Rep. Rokita, Todd [R-IN-4] | R · IN | | Jun 21, 2017 |

## Committee Activity

| Committee | Chamber | Activity | Date |
|---|---|---|---|
| Energy and Commerce Committee | House | Referred to | Mar 31, 2017 |

## Subjects & Policy Tags

**Policy Area:**

Health

## Related Bills

| Bill | Relationship | Last Action |
|---|---|---|
| 115 S 404 | Identical bill | **Feb 15, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. |

## Summary (as of Mar 27, 2017)

This bill amends the Federal Food, Drug, and Cosmetic Act to revise provisions regarding Food and Drug Administration (FDA): (1) inspections of establishments that manufacture or process medical devices, and (2) certification of medical devices for export.

The biannual inspection schedule for medical device establishments handling higher risk devices is replaced with a risk-based schedule. In establishing the risk-based schedule, the FDA must consider an establishment's participation in international medical device audit programs.

The FDA must adopt a uniform process and uniform standards for inspections of domestic and foreign medical device establishments.

Upon request, the FDA must provide to the person in charge of a medical device establishment feedback regarding the person's proposals to address issues identified during an inspection.

The FDA must provide the basis for denying requests for certification of products for export as meeting FDA requirements for domestic products. A person denied such a certification may request supervisory review of that decision.
Products from a medical device establishment that an inspector found to be contaminated or insanitary may be certified for export if the person in charge of the establishment has agreed to a plan to correct the issues identified during the inspection.

## Actions Timeline

- **Mar 31, 2017:** Referred to the Subcommittee on Health.
- **Mar 27, 2017:** Introduced in House
- **Mar 27, 2017:** Referred to the House Committee on Energy and Commerce.