

# Food and Drug Administration Safety and Innovation Act (FDASIA)



The Food and Drug Administration Safety and Innovation Act (FDASIA), signed into law on July 9, 2012, expands the FDA's authorities and strengthens the agency's ability to safeguard and advance public health by:

- **Giving the authority to collect user fees** from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products;
- **Promoting innovation** to speed patient access to safe and effective products;
- **Increasing stakeholder involvement** in FDA processes; and
- **Enhancing the safety of the drug supply chain.**

To help the public keep track of the agency's progress on these and other provisions, we've established a 3-year implementation plan (</about-fda/fda-track-agency-wide-program-performance/fdasia-track>), which is planned to be updated on a monthly basis.

Below are just some of the accomplishments FDA has achieved since the law was passed in 2012.

## User Fees

FDASIA includes the fifth authorization of the Prescription Drug User Fee Act (PDUFA), first enacted in 1992, and the third authorization of the Medical Device User Fee Act (MDUFA), first enacted in 2002. Both programs have provided steady and reliable funding to maintain and support a staff of trained reviewers who must determine whether a proposed new product is safe and effective for patients within a certain time period. The new user fee programs for generic drugs and biosimilar biological products build on the successes of these two established user fee programs.

- Prescription drug provisions (PDUFA V) (</industry/prescription-drug-user-fee-act-pdufa/pdufa-v-fiscal-years-2013-2017>).
- Medical device provisions (MDUFA III) (</medical-device-user-fee-amendments-mdufa>).

- [Generic Drug User Fee Amendments of 2012 \(GDUFA\) \(/generic-drug-user-fee-amendments\)](#)
- [Biosimilar User Fee Act \(BsUFA\) \(/biosimilar-user-fee-act-bsufa\)](#)

## Innovation

FDASIA gave FDA a new and powerful expedited drug development tool, known as the ["breakthrough therapy" designation \(/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-breakthrough-therapies\)](#). This new designation helps FDA assist drug developers to expedite the development and review of new drugs with preliminary clinical evidence that indicates the drug may offer a substantial improvement over available therapies for patients with serious or life-threatening diseases. To provide more information about this and other expedited approval programs, FDA has released the draft guidance [\*Expedited Programs for Serious Conditions – Drugs and Biologics \(/media/86377/download\)\*](#).

FDASIA also sought to further medical device innovation. The FDA has released a [draft guidance \(/media/81792/download\)](#) on the process for approving applications for clinical investigations of medical devices, and is also using its authority under FDASIA to review "direct" de novo device submissions.

## Stakeholder Engagement

FDA works to ensure that interested parties have a variety of opportunities to provide input to FDA decision-making, and stakeholder engagement is an agency priority. FDASIA recognized the value of patient input to the entire drug development enterprise, including FDA review and decision-making. FDASIA-related stakeholder engagement efforts include:

- FDA initiated a five-year [Patient Focused Drug Development program \(/industry/prescription-drug-user-fee-act-pdufa/enhancing-benefit-risk-assessment-regulatory-decision-making\)](#) to learn from patients about the impact of their disease on their daily lives. FDA plans hold at least 20 public meetings (<http://patientnetwork.fda.gov/patient-focused-drug-development-meetings>) over the next 5 years, each focused on a different disease area, and we expect that these gatherings will be attended not only by our staff and patient representatives, but also potential sponsors of new drug development.
- FDA, in collaboration with Office of the National Coordinator for Health IT (ONC) and the Federal Communications Commission (FCC), has set up a public-private working

group under ONC's Health IT committee to gather input from a variety of stakeholders and experts to inform FDA on an appropriate, risk-based regulatory framework pertaining to health information technology, and has already held numerous, productive meetings on this topic. Information on this working group, including a link to a schedule of these meetings, is available on FDA's "[Health IT Regulatory Framework](http://www.fda.gov/medical-devices/digital-health/health-it-risk-based-framework)" ([/medical-devices/digital-health/health-it-risk-based-framework](http://www.fda.gov/medical-devices/digital-health/health-it-risk-based-framework)) website. FDA intends to use the input from this working group in its development of the Health IT Report.

## Drug Supply Chain

With nearly 40 percent of finished drugs being imported, and nearly 80 percent of active ingredients coming from overseas sources, protecting the global drug supply chain and making sure that patients have access to the drugs they need is a priority for FDA.

FDASIA includes a set of provisions, contained in [Title VII of the statute](http://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-title-vii-drug-supply-chain-provisions) ([/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-title-vii-drug-supply-chain-provisions](http://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-title-vii-drug-supply-chain-provisions)), which give FDA new authorities to address the challenges posed by an increasingly global drug supply chain. FDA is working to implement these authorities:

- FDA issued a [proposed](https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-16843.pdf) (<https://s3.amazonaws.com/public-inspection.federalregister.gov/2013-16843.pdf>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) and [final rule](https://www.federalregister.gov/articles/2014/05/29/2014-12458/administrative-detention-of-drugs-intended-for-human-or-animal-use) (<https://www.federalregister.gov/articles/2014/05/29/2014-12458/administrative-detention-of-drugs-intended-for-human-or-animal-use>) to extend the agency's administrative detention authority to include drugs, in addition to the authority that is already in place for foods and devices.
- FDA issued a draft and [final guidance](http://www.fda.gov/media/86328/download) ([/media/86328/download](http://www.fda.gov/media/86328/download)) defining conduct the agency considers delaying, denying, limiting or refusing inspection, resulting in a drug being deemed adulterated.
- In 2013, FDA advocated for higher penalties for adulterated and counterfeit drugs before the U.S. Sentencing Commission – [and succeeded](http://www.ussc.gov/Legal/Amendments/Reader-Friendly/20130430_RF_Amendments.pdf) ([http://www.ussc.gov/Legal/Amendments/Reader-Friendly/20130430\\_RF\\_Amendments.pdf](http://www.ussc.gov/Legal/Amendments/Reader-Friendly/20130430_RF_Amendments.pdf)).
- FDA held a [public meeting](http://www.fda.gov/oc/2013/07/12/fda-holds-public-meeting-to-discuss-how-the-agency-might-implement-other-parts-of-fdasia-to-protect-the-drug-supply-chain) ([/\[!-\\$wcmUrl\('link','UCM357783'\)--\]](http://www.fda.gov/oc/2013/07/12/fda-holds-public-meeting-to-discuss-how-the-agency-might-implement-other-parts-of-fdasia-to-protect-the-drug-supply-chain)) on July 12, 2013, to discuss how the agency might implement other parts of FDASIA to protect the drug supply chain.

- FDA issued a [draft and final guidance \(/media/89926/download\)](/media/89926/download) specifying the unique facility identifier (UFI) system for drug establishment registration.
- FDA issued [annual reports \(/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-705-annual-reports\)](/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fdasia-section-705-annual-reports) outlining the number of domestic and foreign establishments registered and inspected and the percentage of the FDA budget used to fund such inspections.
- FDA issued a [proposed \(https://federalregister.gov/a/2014-10304\)](https://federalregister.gov/a/2014-10304) and [final rule \(http://www.gpo.gov/fdsys/pkg/FR-2015-09-15/pdf/2015-23124.pdf\)](http://www.gpo.gov/fdsys/pkg/FR-2015-09-15/pdf/2015-23124.pdf) regarding administrative destruction of imported drugs refused admission into the U.S.

## Spotlight

- [Track Our Success As We Implement New Law \(http://blogs.fda.gov/fdavoce/index.php/2013/05/track-our-success-as-we-implement-new-law/\)](http://blogs.fda.gov/fdavoce/index.php/2013/05/track-our-success-as-we-implement-new-law/)

## Reports

- [Reports and Plans Mandated by FDASIA \(/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/reports-and-plans-mandated-fdasia\)](/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/reports-and-plans-mandated-fdasia)

## Resources

- [Full text of the FDASIA law \(https://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf\)](https://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf)
- [FDASIA Implementation Tracking Chart \(FDASIA-TRACK\) \(/about-fda/fda-track-agency-wide-program-performance/fdasia-track\)](/about-fda/fda-track-agency-wide-program-performance/fdasia-track)
- [Background on FDASIA \(/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/background-fdasia\)](/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/background-fdasia)