Reporting Allegations of Regulatory Misconduct

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An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices may be doing so in a manner that violates the law. Reporting these allegations can help make the FDA aware of regulatory concerns it may not learn of otherwise. This information can help the FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation.

Anyone may file a complaint reporting an allegation of regulatory misconduct. The FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for the FDA to understand the allegation and act on the report; however you can choose to submit a report anonymously. The FDA will not share your identity or contact information with anyone outside the FDA unless required to do so by law, regulation, or court order.

What kinds of allegations can be reported?

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion. The table below provides some examples of the kind of allegations the FDA has received:

Examples of allegations

- Promotion or advertising of a device outside the FDA-cleared or approved indications for use.
- A device manufacturer fails to submit required reports (/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems) to the FDA for device-related safety concerns, and/or is not conducting required follow up investigations per the regulatory requirements.
- A company's medical devices or manufacturing processes do not meet their design and manufacturing responsibilities.
- Marketing a medical device without the appropriate FDA clearance (510(k)) or approval (PMA).

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- A manufacturer imports medical devices into the United States that do not meet legal requirements for admission to the U.S.
- A third party outside the medical device company forges or falsifies an export certificate to bring medical devices into the U.S.
- A company fails to register and list their medical device products with the FDA, preventing the FDA from having required information about a device on the market.
- A manufacturer knowingly deceives the FDA. For example, the manufacturer hides information from the FDA, or falsifies documents, etc. given to the FDA.

How do I submit an allegation about a medical device manufacturer to the FDA?

You can submit an allegation through the Allegations of Regulatory Misconduct Form (/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form), by email, or by regular mail.

Email:
CDRHDeviceAllegations@fda.hhs.gov (mailto:CDRHDeviceAllegations@fda.hhs.gov)

Regular Mail:
Attention: Allegations of Regulatory Misconduct Team
Office of Regulatory Programs
Center for Devices and Radiological Health
Food and Drug Administration
WO Bldg. 66 RM 1523
10903 New Hampshire Ave
Silver Spring, MD 20993

What information should I include when reporting an allegation of regulatory misconduct?

The following information helps the FDA assess an allegation:

- Medical device(s) in question, including:
  - Name of the company
  - Address and telephone number of the company, if known
  - Name of the device and model (if applicable)
  - Lot numbers/serial numbers/part numbers
  - Unique Device Identifier (UDI), if known
  - Recall numbers
- Detailed description of the allegation with any available supporting documentation

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To report serious adverse reactions, product quality problems, therapeutic inequivalence/failure, and product use errors associated with FDA-regulated drugs, biologic products, medical devices, dietary supplements, infant formula, and cosmetics, visit the MedWatch adverse event reporting webpage (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda). For questions about other medical device topics, please contact the CDRH Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).

If you have questions about submitting an allegation, you may contact the Allegations of Regulatory Misconduct Staff by phone at (240)402-7675 or by email at CDRHDeviceAllegations@fda.hhs.gov (mailto:CDRHDeviceAllegations@fda.hhs.gov).

What happens to allegations of regulatory misconduct submitted to the FDA?

Allegations of regulatory misconduct related to medical devices are reviewed by the Center for Devices and Radiological Health (CDRH). CDRH prioritizes the review of allegations based on the level of potential risks, within the context of an overall benefit-risk profile, to patients. There are different processes based on the type of allegation and the completeness of the information submitted. The following are the general steps CDRH takes after receiving an allegation of regulatory misconduct:

1. If contact information is provided, CDRH sends an acknowledgement letter to the submitter which includes an FDA-assigned identification number for the allegation report. This number is used in all follow-up communication to ensure that the report information is filed together.
2. CDRH assesses the allegation and determines the potential risk to patients, and CDRH will investigate further if warranted. After our assessment, we take appropriate action, which could include:
    - Regulatory actions such as sending a warning letter to the medical device firm, conducting an inspection of the manufacturing facility, or requesting a device recall.
    - Contacting the individual, firm or medical device manufacturer for additional information.
    - Monitoring the allegation using additional sources of reported information (e.g. medical device reports (MDRs), new complaints, inspection reports) to determine any action needed.

How can I find out the outcome of an allegation submitted to the FDA?

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Requests for records of completed investigations can be submitted pursuant to the Freedom of Information Act (FOIA). Please note that FOIA does not require agencies to create new records or to conduct research, analyze data, or answer questions submitted as FOIA requests for records.

Information about how the CDRH Division of Information Disclosure implements the requirements of FOIA is available at CDRH FOIA: How to get records from CDRH (/about-fda/center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh).

Please note that investigations of allegations of regulatory misconduct can be complicated and take time. If you plan to submit a FOIA request (/regulatory-information/freedom-information/how-make-foia-request), we recommend waiting at least 180 days after submitting allegations to the FDA before submitting a FOIA request for related records.

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