

Allegations of Regulatory Misconduct Form

OMB control number: 0910-0769
Approval Expiration Date: 8/31/17

This form is to report an allegation of regulatory misconduct, a claim that a medical device manufacturer or individuals marketing medical devices may be doing so in a manner that violates the law. Submitting an allegation is voluntary, and the form does not have to be complete in order for the allegation to be reviewed.

Please include as much of the following information as possible to help the FDA assess the allegation you are reporting:

Name of the company for which you are submitting an allegation:**Telephone number of the company:****Address of the company:**

*** Name and model (if applicable) of the Medical Device(s) in question:****Lot numbers / serial numbers / part numbers:***** Detailed description of the allegation with any available supporting documentation:**

Your Name:

Your Email:

Please email any document attachments to OCMedicalDeviceCo@fda.hhs.gov (<mailto:OCMedicalDeviceCo@fda.hhs.gov?subject=Allegation%20of%20Regulatory%20Misconduct%20File%20Attachments>). Please send attachments from your email address used above.

More in [Reporting Allegations of Regulatory Misconduct](#)
(</MedicalDevices/Safety/ReportingAllegationsofRegulatoryMisconduct/default.htm>)

- ▶ **[Allegations of Regulatory Misconduct Form](#)**
(</MedicalDevices/Safety/ReportingAllegationsofRegulatoryMisconduct/ucm526129.htm>)