Allegations of Regulatory Misconduct Form

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This form is to report an allegation of regulatory misconduct to FDA's Center for Devices and Radiological Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device/electronic product manufacturer or individuals marketing medical devices/ electronic products regulated by CDRH may be doing so in a manner that violates the law.

Submitting an allegation is voluntary. We encourage individuals submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

We have indicated which fields are required for a submission with asterisks. We recommend that you provide as much information and detail as possible to assist with our investigation and follow-up. This information will help FDA identify the specific products implicated in the allegation and the entities associated with their manufacturing, promotion, and/or distribution.

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* Indicates which fields are required for submission

*** Name of the company about which you are submitting an allegation:**

Company Name

Telephone number of the company:

Company Phone

Company Website - Web address of the company about which you are submitting an allegation:

Company Website

Address of the company:

Company Street Address

*** Name and model (if applicable) of the Medical Device(s) / Electronic Products in question:**

Device / Electronic Product Name

Lot numbers / serial numbers / part numbers:

Lot, Serial, or Part Numbers

Unique Device Identifier (UDI) number:

UDI Number

*** Detailed description of the allegation with any available supporting documentation:**

Description

Your Name:

Your Name

Your Email:

Your Email

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Please email any document attachments to CDRHDeviceAllegations@fda.hhs.gov (mailto:CDRHDeviceAllegations@fda.hhs.gov). Please send attachments from your email address used above.

Was this helpful? Yes No

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