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MedWatch Online Voluntary Reporting Form

Begin report as a:

Health Professional
(FDA Form 3500) (</scripts/medwatch/index.cfm?action=professional.reporting1>)

Consumer/Patient
(FDA Form 3500B) (</scripts/medwatch/index.cfm?action=consumer.reporting1>)

 [Frequently Asked Questions \(/scripts/medwatch/index.cfm?action=reporting.faqs\)](/scripts/medwatch/index.cfm?action=reporting.faqs)

What to Report to FDA MedWatch:

Use the MedWatch form to report adverse events that you observe or suspect for human medical products, including serious drug side effects, medication errors/product use errors, product quality problems, and therapeutic failures for:

- Prescription or over-the-counter medicines, as well as medicines administered to hospital patients or at outpatient infusion centers
- Biologics (including blood components, blood and plasma derivatives, allergenic, human cells, tissues, and cellular and tissue-based products (HCT/Ps))
- Medical devices (including in vitro diagnostic products)
- Combination products
- Special nutritional products (infant formulas, and medical foods)
- Cosmetics
- Foods/beverages (including reports of serious allergic reactions)

What Not to Report to FDA MedWatch:

- Tobacco: Tobacco product problems should be reported to the [Safety Reporting Portal](#)

(<https://www.safetyreporting.hhs.gov/fpsr/WorkflowLoginIO.aspx?metinstance=D432215BCD68831461E102E11540AD46662CAE5D>).

- Vaccines: Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at <https://vaers.hhs.gov/esub/index> (<https://vaers.hhs.gov/esub/index>).
- Investigational (study) drugs
(<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf>): Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.
- Mandatory reporting by regulated industry:
 - Drugs and Biologics
(<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm>)
 - Applicable Regulations (<http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085692.htm>)
 - Devices (<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm#howtoreport>)
- Reporting on Dietary Supplements (<http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/default.htm>)
- Reporting on Veterinary Medicine Products
(<http://www.fda.gov/animalveterinary/safetyhealth/reportaproblem/ucm055305.htm>)
- Reports FDA Does Not Handle
(<http://www.fda.gov/Safety/ReportaProblem/QuestionsandAnswersProblemReporting/default.htm#problems>) (e.g. CPSC, FTC, State Health Departments) and Where to Send Them







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Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players
(<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/ViewingFiles/default.htm>).

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- [For Government \(http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm\)](http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm)
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