

Santa Cruz County 2003 Health Almanac

Medical Product Safety

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Agencies and Information Sources

Santa Cruz County (SCC) Health Services Agency - <http://www.santacruzhealth.org/>

The Health Services Agency (HSA) exists to protect and improve the health of the people in Santa Cruz County. The Agency provides programs in Environmental Health, Public Health, Medical Care, Substance Abuse Prevention and Treatment, and Mental Health.

California Department of Health Services - <http://www.dhs.ca.gov/default.htm>

To Protect and Improve the Health of All Californians

California Health Interview Survey - <http://www.chis.ucla.edu/index.html>

The California Health Interview Survey (CHIS) is the largest state health survey conducted in the United States. Every two years, CHIS plans to collect information on the health and health care needs of California's diverse population.

Centers for Disease Control and Prevention - <http://www.cdc.gov/default.htm>

CDC's Mission is to promote health and quality of life by preventing and controlling disease, injury, and disability.

Medical Product Recalls – See: <http://www.fda.gov/opacom/7alerts.html>

Background and Definitions

Recalls are actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. A Class II recall is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. A Class III recall is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

A market withdrawal occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

A medical device safety alert is issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.