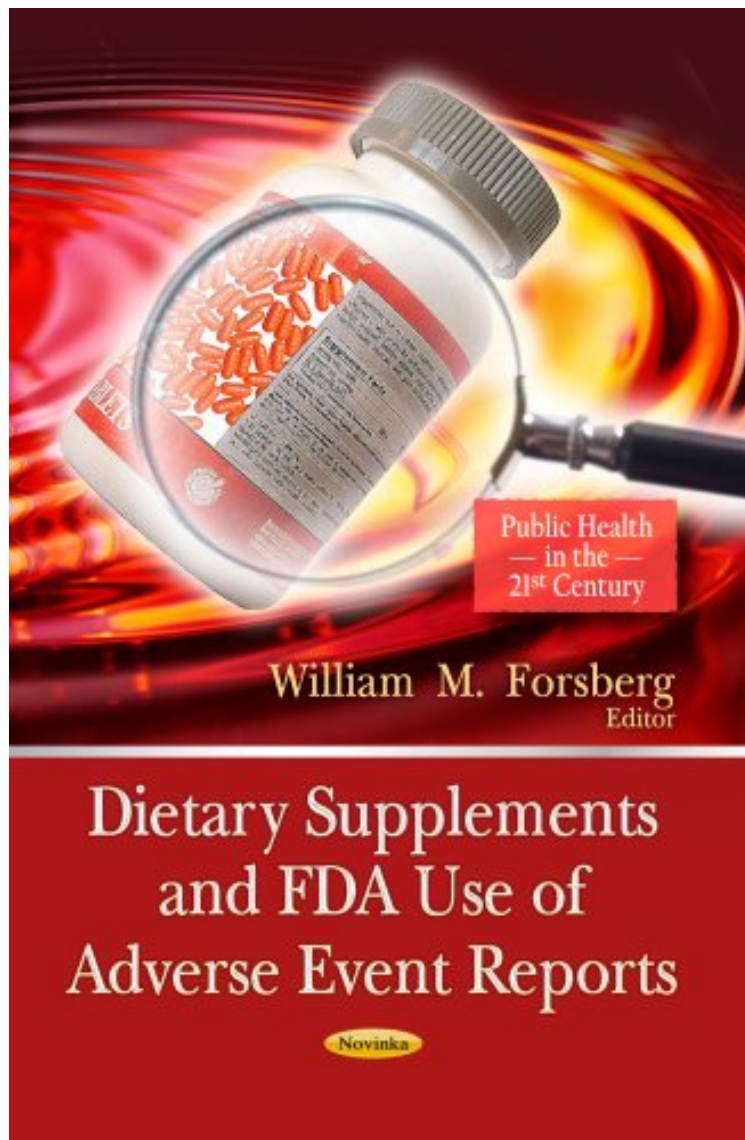


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Dietary Supplements and FDA Use of Adverse Event Reports (Public Health in the 21st Century):

Manufacturers, packers, and distributors of dietary supplements in the United States are required to report information about serious adverse effects associated with the use of these supplements to the Food and Drug Administration (FDA). The FDA carefully considers all the available safety information submitted to the agency before a product is approved. However, unexpected and sometimes serious safety problems can emerge once a product goes to market and is used by millions of people. As a result, post-market safety monitoring, that is, analysing information on products once they go to market, is a critical part of the FDA's responsibilities. The public provides an important source of such safety information. Health care facilities, practitioners, and patients submit reports to the FDA and to manufacturers on adverse events, medical errors, and product quality problems observed during the use of a product. This book examines the number of adverse event reports the FDA has received since 2008; their source and types of products identified, and the actions the FDA has taken to ensure that firms are complying with adverse event report requirements.