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REPORTS OF CASES ARGUED AND DECIDED IN THE SUPREME COURT OF THE UNITED STATES VOLUME 35

RareBooksClub. Paperback. Book Condition: New. This item is printed on demand. Paperback. 26 pages. Original publisher: Washington, D. C. : U. S. General Accounting Office, 2002 OCLC Number: (OCoLC)53100369 Subject: Dietary supplements -- United States -- Safety measures. Excerpt: . . . or prescription drugs are the same, the authority to regulate dietary supplements, and to take action on safety concerns, is different from that for drugs. When FDA has health concerns about an over-the-counter ingredient, or combination of ingredients, the agency may determine that it is not generally recognized as safe and effective, and may issue a regulation or take other action to prohibit further marketing. FDA is not required to find that an over-the-counter drug is unsafe or dangerous to remove it from the market. In the case of dietary supplements, more significant safety concerns would have to be identified. For example, FDA is authorized to take regulatory action against a dietary supplement if its use would present a significant or unreasonable risk of illness under recommended conditions of use. If FDA were to take such action, however, it must be prepared to prove its allegations either in an administrative hearing or court. Unlike its regulation of over-the-counter drugs, FDA has the burden of proving that a dietary supplement presents a significant or unreasonable risk before it can be taken off the market. These differences in regulatory standards are reflected in differences in actions taken for similar or identical ingredients. Specifically, FDA has concluded that two categories of products are not generally recognized as safe and effective and cannot be marketed for over-the-counter use. These categories of products, however, may be used in dietary supplements. First, in September 2001, FDA ruled that over-the-counter drugs containing ephedrine and related alkaloids in combination with an analgesic or stimulant would be...



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