

GMP, GCP & QUALITY CONTROL

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Dietary supplements: What's in a name? What's in the bottle?

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The Dietary Supplement Health and Education Act of 1994 (DSHEA), which arbitrarily classified herbals and other medicinal products as dietary supplements, obscured fundamental differences between two classes of products. Authentic supplements to the diet, such as multivitamins or calcium, have nutritional value and are safe. Herbals are used worldwide as medicines, they do not supplement the diet, they may cause severe adverse events and they should be regulated as medicines. DSHEA also prevented the Food and Drug Administration (FDA) from effectively regulating herbal supplements as medicines. One consequence of weak FDA regulatory oversight is the poor quality of herbals. FDA inspections of manufacturing facilities have revealed violations of good manufacturing practices in over half of facilities inspected, including unsanitary conditions and lack of product specifications. Moreover, many "all natural" herbals marketed for weight loss, enhancement of sexual health and improving sports performance are adulterated with prescription and over-the-counter medications that have caused adverse cardiovascular events. New procedures to authenticate the identity of plants used in herbals will neither detect adulteration by medications nor provide assurance of appropriate pharmacological activity or safety. Non-vitamin, non-mineral supplements should be regulated as medicines, but revision or repeal of DSHEA faces strong opposition in congress. The marketing of botanical supplements is based on unfounded claims that they are safe and effective. Health professionals need to inform patients and the public that there is no reason to take herbal medicines whose composition and benefits are unknown and whose risks are evident.

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