TABLE 10.1 (*Continued*)

Herbal Drug Approval Rules in Different Countries

U.S.A.	Since 1994, herbal medicines have been regulated under the "Dietary Supplement Health and Education Act of 1994." On the basis of this law, herbal medicines are not evaluated by the FDA, and most important, these products are not intended to diagnose, treat, cure, or prevent diseases. The U.S. FDA issued its first botanical drugs approval guidelines in August 2000. The mission of the NCCAM is, in part, to conduct rigorous research on CAM practices to evaluate the benefits and risks of CAM agents, so as to optimize their effect on human diseases or conditions. NCCAM groups CAM practices in five major domains: biologically based therapies, manipulative and body-based methods, mind-body interventions, energy therapies, and alternative medical systems. Biologically based CAM agents are regulated under the codes of DSHEA 1994. This regulation includes botanicals and their constituents, vitamins, minerals, and amino acids. The U.S. FDA characterizes botanicals and other dietary agents according to their use, not according to their composition. If the intended use is to "promote health," the agent is viewed as a dietary supplement; if the intended use is to treat or prevent a disease, the agent is considered to be a drug.

Abbreviations: CAM, complementary and alternative medicine; DSHEA, Dietary Supplement Health and Education Act; EEC, European Economic Community; ESCOP, European Societies' Cooperative of Phytotherapy; HPB, Health Protection Branch; NCCAM, National Center for Complementary and Alternative Medicine; OTC, over the counter; U.S. FDA, United States Food and Drug Administration; WHO, World Health Organization.

Usually, the active principles responsible for their pharmacological action are unknown. One basic characteristic of phytotherapeutic agents is that they normally do not possess an immediate or strong pharmacological action. For this reason, phytotherapeutic agents are not used for emergency treatment. Other characteristics of herbal medicines are their wide therapeutic use and great acceptance by the population. In contrast to modern medicines, herbal medicines are frequently used to treat chronic diseases. Combinations with chemically defined active substances or isolated constituents are not considered to be herbal medicines. It is important to note that, although homeopathic preparations may frequently contain plants, they are not considered to be herbal medicines.

Compared with well-defined synthetic drugs, herbal medicines exhibit some marked differences, namely:

- The active principles are frequently unknown.
- Standardization, stability, and quality control are feasible but not easy.
- The availability and quality of raw materials are frequently problematic.
- Well-controlled double-blind clinical and toxicological studies to prove their efficacy and safety are rare.
- Empirical use in folk medicine is a very important characteristic.
- They have a wide range of therapeutic use and are suitable for chronic treatments.
- The occurrence of undesirable side effects seems to be less frequent with herbal medicines, but well-controlled randomized clinical trials have revealed that they also exist.
- They usually cost less than the synthetic drugs.