TABLE 10.1

Herbal Drug Approval Rules in Different Countries

Argentina	The Herboristerias are authorized for sale as plant drugs but not as mixtures. Mixtures of plant drugs are controlled (Law No. 16.463). In 1993, a Ministry of Health regulation determined the obligatory registration of medicinal herbs. The Argentinian National Pharmacopeia established control over the existence of crude extracts, extracts, or fractions of complex chemical composition, and pure active principles. About 889 monographs exist in Argentina. About 56 describe crude drugs alone and 33 describe extracts or fractions. However, there is lack of control of raw materials, lack of control over the wild plants, lack of scientific criteria for the collection of plants, and lack of control over methods of drying, conservation, or grinding.
Australia	The Australian Parliament established the Working Party on Natural and Nutritional Supplements to review the quality, safety, efficacy, and labeling of herbal and related products (Therapeutic Good Act, 1990). The act provides "that traditional claims for herbal remedies be allowed, providing general advertising requirements are complied with and providing such claims are justified by literature references."
Brazil	In 1994, the Ministry of Health created a commission to evaluate the situation of phytotherapeutic agents in Brazil. The commission proposed a directive based mainly on German and French regulations and on WHO guidelines for herbal drugs. In 1995, "Directive Number 6" established the legal requirement for the registration of herbal drugs and defined the phytopharmaceutical product as "a processed drug containing as active ingredients exclusively plant material and/or plant drug preparations. They are intended to treat, cure, alleviate, prevent, and diagnose diseases."
Canada	In 1986, the Canadian HPB constituted a special committee (three pharmacists, two herbalists, one nutritionist, and one physician) and classified herbal drugs as "Folk Medicine." The regulation is based on traditional uses, as long as the claim is validated by scientific studies. In 1990, the HPB listed 64 herbs that were considered to be unsafe. In 1992, the HPB submitted a regulatory proposal to the Canadian Parliament and listed another 64 herbs that were considered to be adulterants. The Canadian regulatory system is consistent with the WHO guidelines for the assessment of herbal medicines.
Chile	In 1992, the Unidad de Medicina Tradicional was established with the objective of incorporating traditional medicine with proven efficacy into health programs (Law No. 19.253, October 1993). Directive No. 435/81 defined herbal drugs with therapeutic indication claims and/or dosage recommendations as being drugs restricted for sale in pharmacies and drug stores. Registration for marketing authorization is needed for herbal products. Natural products are legally differentiated as follows: (*i*) drugs intended to cure, alleviate, or prevent disease; (*ii*) food products for medicinal use and with therapeutic properties; and (*iii*) food products for nutritional purposes.
China	In China, until 1984, there was virtually no regulation of pharmaceuticals or herbal preparations. In 1984, the People's Republic implemented the Drug Administration Law, which said that traditional herbal preparations were generally considered "old drugs" and, except for new uses, were exempt from testing for efficacy or side effects. The Chinese Ministry of Public Health would oversee the administration of new herbal products.

(*Continued*)