Table 2: Herbs and Herbal Materials Approved as Over-the-Counter (OTC) Drug Ingredients by the U.S. FDA*

Herb Common Name	Latin Name	Approved Use
Capsicum fruit oleoresin	*Capsicum* spp.	Topical analgesic
Ipecac root	*Cephaelis ipecacuanha*	Emetic
Psyllium seed husk	*Plantago spp.*	Bulk laxative
Senna leaf and fruit	*Senna alexandrina; Cassia senna*	Stimulant laxative†
Slippery elm bark	*Ulmus rubra*	Demulcent
Witch hazel bark	*Hamamelis virginiana*	Astringent

* Herbs and herb materials refers to whole plants and/or plant parts, or their derived chemically complex products (e.g., oleoresin capsicum), but not single chemical entities (e.g., capsaicin, the primary active ingredient in capsicum oleoresin, approved as both an Rx and OTC drug, but not considered "herbal" although it is plant-derived). Further, pure compounds from herb-derived oils, although approved for OTC drug use, are not considered "herbal;" these include eucalyptol from eucalyptus leaf, menthol from peppermint leaf oil, and thymol from thyme leaf oil.

† In May 2002, the FDA issued a regulation effective November, 2002, deeming aloe (*Aloe ferox*, A. spp.) and cascara sagrada (*Rhamnus purshiana*) as laxative ingredients not generally recognized as safe for use as ingredients in OTC drug products. This regulation was based on the failure of members of the OTC drug and the herb industries to provide certain information requested by the FDA in June 1998 to help determine the safety of these ingredients. The FDA's request was based on previous research suggesting potential carcinogenicity associated with anthraquinone laxatives. Data on the potential safety of senna was submitted by members of the OTC drug industry, thereby allowing senna-based laxative preparations to stay on the market until the FDA's determination is issued (FDA, 2002c). The American Herbal Products Association and the International Aloe Science Council filed a petition with the FDA requesting a stay of this order until new safety data on aloe and cascara could be filed and considered (AHPA, 2002).