and composition of its dietary supplements. This change places more accountability on the industry and should increase consumers' confidence in the quality of dietary supplements, according to the FDA.

Between 1990 and 1997, the use of botanical medicines in the United States increased by 380%. By 2010, the global retail sale of botanical dietary supplements amounted to more than $25 billion. Outside the United States, the World Health Organization reports that 75%–85% of the world's population continues to rely on botanical medicines dispensed by traditional healers for primary healthcare, as they have always done.

In 2004, the FDA established an industrial guideline for botanical drugs (Botanical Drug Guidance) as an effort to take the initiative in the botanical drug market. The first botanical drug approved by the FDA was Veregen® (MediGene, Inc.), a treatment for genital and perianal warts that is derived from green tea. A number of years later, the FDA approved another New Drug Application (NDA) for the drug Fulyzaq™ (Napo Pharmaceuticals), an indicator drug for human immunodeficiency virus (HIV)-associated diarrhea, extracted from the blood-red latex of the South American croton tree. GW Pharmaceuticals, an English company, developed Sativex (Oromucosal Spray), a marijuana extract efficacious for rigidity due to multiple sclerosis. GW Pharmaceuticals raised $11 million with Sativex. In Europe, they use the term herbal medicinal product (HMP) to encompass all drugs that contain one of more kind of herbal substances in the herbal preparation. The Chinese developed Traditional Chinese Medicine (TCM), a prescription of their traditional medicines, based on their own experiences of its usage, and eastern ideas.

There have been numerous attempts to bring botanical drugs to the market through FDA approval, including more than 500 pre-IND meetings and IND applications, with limited success in reaching the final NDA stage. In fact, only two NDAs have been approved by the FDA so far. The FDA requires "adequate and well-controlled" multicenter clinical studies on any new drug candidate to document and support its safety and efficacy and imposes the maximum level of scrutiny prior to approval. It is crucial for these efficacy studies to have a well-defined target population (according to the FDA protocol's eligibility criteria), proper experimental controls (such as placebo or active treatment), appropriate outcome measures (agreed upon by the FDA), independent monitoring, and accurate analysis. Consequently, the single most common reason that any new drug candidate, including botanical drugs, fails to reach the NDA step is the failure to present statistically significant evidence for having efficacies of clinical relevance. Unrealistic expectations are often set forth by drug sponsors with insufficient experience with a drug development program, for multiple reasons, and the resulting miscommunication could hinder the drug approval process. For one, the initial stages of IND development are relatively less strict, and this may falsely suggest to new drug sponsors that botanical drugs, compared with conventional synthetic drugs, are less rigorously evaluated by the FDA. Another reason for drug sponsors to have unrealistic expectations is the confusion that arises from the lack of internationally standardized regulatory requirements for botanicals. In other words, many non-U.S. botanical drug sponsors, especially those that have no experience in fielding a drug development operation in the United States, are not aware of the practical differences in regulations between the United States and a foreign market. As an anecdote, some sponsors do not reconcile the fact that "raw data" (chemistry, nonclinical safety testing, or clinical study databases), instead of data summaries or "expert" opinion, is required by U.S. regulations.