In early March 2011, the U.S. Food and Drug Administration (“FDA”) significantly increased its enforcement rhetoric against all companies manufacturing, importing, or distributing prescription cough, cold, or allergy drugs that have been distributed for years in the U.S. with little if any adverse events or safety problems. FDA suddenly alleged in letters to drug companies that their products were “unapproved new drugs” which can no longer be marketed legally in the United States. Although FDA had taken numerous similar actions against much more dangerous drug classes or categories (e.g., those containing highly addictive narcotic active ingredients) since its “Unapproved Drugs Initiative” –introduced June 2006 – this recent action is the first taken against such a “minimally-dangerous drug category – allergy drugs”, says Benjamin England, Founder of FDAImports.com, LLC, a food and drug regulatory consulting firm in the United States. “FDA is extending its ‘regulatory self’ and its enforcement powers, as far as possible while they have enhanced resources under the Obama Administration and, perhaps more importantly, political cover,” concluded England.

FDA has over a 100-year history in regulating drug safety, but a shorter one governing drug efficacy, which is what this recent FDA enforcement action is about. “Because these are prescription drugs, which would likely be subject to ‘Barak-O-care’ style entitlements and subsidies, the government is already paring back on medicines doctors may use to treat their patients,” England argues. Benjamin England, a 17-year FDA veteran and former regulatory counsel to the FDA’s top enforcement official, has a view that is perhaps novel. Drug efficacy requirements for new drug approvals have been the statutory and regulatory standard since 1968. “While that’s true,” acknowledges England, “at FDAImports.com, we believe doctors, and not government agencies, should determine whether an otherwise safe drug is effective for their patients.”

In 1938, the first enactment of the Food Drug and Cosmetic Act (“FDCA”), at least as we would recognize it today, gave to FDA authority to review and approve the safety, not just the truthfulness claims or purity of drug products. Nearly thirty years later amendments to the FDCA mandated FDA review and evaluate the efficacy of new drugs before permitting those drugs to be marketed. By then, however, FDA had already approved literally thousands of drugs under the older, safety standard, sans efficacy reviews. Following the 1962, amendments to the FDCA, FDA initiated the Drug Efficacy Study Implementation (“DESI”) program, which set up drug panels to review the available data supporting efficacy of drugs FDA had previously approved. “These cough, cold and allergy prescription drugs failed the FDA test on efficacy, so they are out,” says England, and so they are no longer available to licensed physicians. FDA is ordering the companies making, importing and distributing them to cease and desist or face significant penalties or even criminal sanctions.

“The drug industry needs to recognize this as a warning,” suggests Mr. England, “with a bloated budget, FDA now has the resources to press its policies and to enforce its view that products previously found safe (by the Agency) are ineffective, even if your doctor thinks otherwise.” Mr. England notes that this FDA is not beyond pressing its views into other areas of regulation, citing to President Obama’s and the First Lady’s recent public addresses regarding the health of
children and the effect of eating too many fatty-foods. FDA-regulated industry needs to take note when Congress grants to FDA broad sweeping regulatory authority over tobacco, or mandatory recall authority for foods, or the right to collect fees when it decides to re-inspect a company because of concerns the inspector noticed the first time.

FDA has more authority and resources now than it ever has in its 105-year history. FDAImports.com, LLC watches for increased FDA enforcement authorities and trends in FDA regulatory activity and regularly assists manufacturers, importers and distributors in complying with the new ‘hoops and hurdles’. FDAImports.com, LLC is a food and drug consulting firm with years of proven regulatory experience in interpreting and applying US FDA’s expanding laws and regulations. Let FDAImports.com, LLC show you ‘the way through’ FDA’s regulatory enforcement powers.