Congress of the United States

Washington, DC 20515

July 16, 2007

The Honorable Andrew C. Von Eshenbach
Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Von Eschenbach:

We write in regards to the Food and Drug Administration's (FDA) attention on certain classes of older prescription pharmaceuticals that have long histories of marketing without any apparent safety or efficacy concerns.

We recognize that these drugs have been marketed outside of the present drug approval process. However, as the drug approval process has evolved, the Agency has acquiesced to the continued marketing of these products as a matter of enforcement discretion.

Congress, via the appropriations process, has repeatedly urged FDA to work cooperatively with industry in search of a solution to this regulatory anomaly. Previous requests for a "Prescription Drug Monograph" were met with opposition from the Agency due in large part to suggested resource allocation issues.

Instead, FDA referred to its Compliance Policy Guide (CPG) on marketed, unapproved drugs -- finalized in June of 2006. However, the CPG stops short of outlining a course to protect public health without imposing undue burdens on consumers or disrupting the market unnecessarily. The CPG does not adequately address our concerns on the regulatory position of the FDA. Rather, it leaves products, companies, and patients in limbo based on undefined risk-based decisions to be made at some point in the future by the FDA.

It is our understanding that the Branded Pharmaceutical Association (BPA) has been working with FDA for over 4 years, including a recent meeting with you and your staff, in an attempt to find common ground for alternative, cost effective methods that will allow FDA to deem these so called "Legacy Drugs" as approved.

As you know, "Legacy Drugs" are composed of FDA approved ingredients, manufactured in FDA licensed and inspected facilities utilizing current Good Manufacturing Practices, have no known safety concerns, and have been prescribed by doctors for at least 25 years. Virtually everyone who has taken medicines for cough, allergy, asthma, or used topical products for a rash, itching or hemorrhoids has used one of these type products.

The small businesses that still produce these products employ several thousand people throughout the U.S. They are excellent contributors to their local economies as well as the national economy. Through their efforts, these cost effective alternatives to new medications have continued to be available saving patients, insurance companies, and state/federal programs millions of dollars in medical expenses.

While we understand that the Agency is under great pressure to produce a solid demonstration of enforcement to the public in the wake of recent safety concerns, it is essential that enforcement measures be directed towards activities that are most likely to improve the public health.

We seek your assurance that "Legacy Drugs" will not be unfairly targeted before Congress has the opportunity to afford due process. We look forward to working with you to find a reasonable solution to this issue.

Sincerely,