

# AMERICAN FREE TRADE ASSOCIATION

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January 26, 2007

**SUBMITTED ELECTRONICALLY AND VIA OVERNIGHT DELIVERY**

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**COMMENTS IN RESPONSE TO PROPOSED REGULATIONS ON ELECTRONIC  
REGISTRATION AND LISTING SUBMISSIONS  
Docket Number 2005N-0403**

Dear Sirs:

In response to the Federal Register notice of August 29, 2006 proposing amendments to the FDA's drug establishment and listing regulations, the American Free Trade Association (AFTA) respectfully provides the following comments.

**Background Information**

The American Free Trade Association is a not-for-profit trade association of independent American importers, distributors, retailers and wholesalers, dedicated to preservation of the secondary or parallel market to assure competitive pricing and distribution of genuine and legitimate brand-name goods

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for American consumers. AFTA has been an active advocate of parallel market interests for over twenty years. It has appeared as *amicus curiae* in the two leading Supreme court cases affirming the legality of parallel market trade under the federal trademark, customs and copyright acts (the *Kmart v. Cartier* case, 485 US 176 (1988) and *Quality King Distributors v. L Anza Research International, Inc.* 523 US 123 (1998)) and in numerous lower court decisions.

## 2. Summary Position

The American Free Trade Association welcomes the opportunity to comment on the U.S. Food and Drug Administration's (FDA's) proposed regulations in connection with electronic registration and listing of drugs and related pharmaceutical products. AFTA broadly supports the FDA's proposed regulations, which include full disclosure on product labeling of NDC numbers and the creation of a publicly accessible database of related labeling and registrant information.

## 3. Further Discussion

AFTA is a national trade association representing importers and distributors of genuine, brand name products throughout the wholesale or secondary marketplace. AFTA's members aggressively work to ensure that the products they distribute are safe, unadulterated and approved for distribution in the United States. Oftentimes, these efforts are hindered because the information needed to confirm the lawfulness of such products is not available publicly or in the ordinary course of business between buyers and sellers of the goods. Moreover, many manufacturers elect to selectively distribute information, such as NDC numbers, which is needed

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to verify compliance with those FDA regulations that require OTC drug listing as a condition of domestic distribution. These manufacturers only disclose applicable NDC information to those parties specifically authorized by the manufacturer itself, permitting the manufacturer to dictate product pricing and to strategically limit distribution. In this way, drug manufacturers are able to prevent competition and prevent alternative sources of OTC pharmaceuticals from offering American consumers the same, genuine drugs, at more competitive prices and at more retail establishments.

As a result of the fact that the FDA does not already require or otherwise facilitate the disclosure of NDC information which is needed for distributors to verify that a particular product may be lawfully distributed in the United States, the resulting public perception (and in fact the reality) is that the FDA procedures, whether by design or accident, champion drug manufacturers to the detriment of American consumers. The Agency policies have operated to diminish or deprive American consumers of a freely competitive marketplace by providing drug manufacturers with a power over information required for distribution which is sufficient to monopolistically control distribution of critical pharmaceutical products. Because under existing regulations regulated establishments are not required to print NDC numbers on product labeling and because the FDA does not make these numbers publicly available (nor does it link any NDC number with the concomitant labeling on any accessible database or website), it has often been incredibly difficult, if not ultimately impossible, to prove to FDA, at the time of importation, that any product being imported has, in fact, been approved for distribution within the United States and otherwise complies with the U.S. Food, Drug and Cosmetic Act.

Although AFTA is certain that the FDA has no intention of compromising

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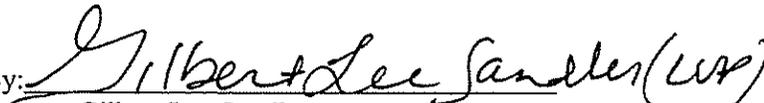
its responsibilities at the border simply because of public perception or because of a health and safety requirement which necessarily and unavoidably has an anti-competitive impact, there is no doubt that the best interests of American consumers are certainly served by ensuring that the products they have access to are those actually approved by the FDA for distribution in the United States. It is also, without a doubt, in the best interests of American consumers to permit unfettered distribution of genuine, unadulterated, over-the-counter pharmaceuticals. It is, therefore, resoundingly positive and reassuring that the FDA has proposed regulations that would no longer provide manufacturers with a tool (i.e., selective disclosure of critical information such as NDC numbers) which is usable to eliminate competition and control distribution of genuine over-the-counter drug products which are safe, unadulterated, and fully compliant with U.S. laws and regulations.

## Conclusion

If you have any concerns or questions regarding these comments, or if you would like to discuss these matters further with the American Free Trade Association, please feel free to contact the undersigned directly at any time.

Sincerely,

American Free Trade Association

By:   
Gilbert Lee Sandler  
General Counsel

Cc: Board of Directors