AMERICAN FREE TRADE ASSOCIATION

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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Prior Notice Regulations under the BioTerrorism Act

Dockets Nos. 02N-0276 and 02N-0278

Dear Sirs:

The American Free Trade Association (AFTA) is an association of U.S. businesses that provide American consumers with cost-effective, genuine brand name products. AFTA members are concerned that the FDA's Interim Final BioTerrorism Regulations (BTA Regulations) will impede free trade, even if they do not explicitly prohibit the free flow of goods. These concerns arise because the FDA has determined that importers of U.S. Goods Returned must provide domestic manufacturer's registration numbers on the Prior Notice submissions, even if the importer is not related to the manufacturer and, in fact, directly competes with it. These comments are, therefore, submitted on behalf of AFTA in the anticipation that, by working together with the FDA, final BTA Regulations may be implemented that more particularly protect this critical American industry.

Background of the American Free Trade Association

AFTA is an incorporated, not-for-profit trade association representing the legitimate needs and interests of the domestic parallel market industry. AFTA, formed over twenty years ago, is a trade association of retailers, distributors, wholesalers and importers committed to preserving free trade within the international marketplace. Many of AFTA's members are small businesses that are located throughout the United States and employ thousands of American citizens. AFTA's members supply genuine merchandise - manufactured under the authority of the U.S. manufacturer - throughout the United States to discount and other retailers, including the mass discount retailers, "outlet" shops, and

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neighborhood stores that are favored by millions of American purchasers. The tax-paying businesses directly involved in parallel market distribution and sale employ tens of thousands of U.S. residents and are, arguably, among the strongest components of the American economy.

General Discussion and Comments

On December 11, 2003, FDA Commissioner Mark McClellan made the following statement as he released the Policy Guide for enforcement of the Prior Notice regulations:

> "Our intention all along has been to implement the Bioterrorism Act in a way that would protect consumers without obstructing the food imports, on which we depend for 20 percent of all fresh produce and up to 60 percent of all the seafood consumed in the U.S. The goal of the transition policy is to provide complete clarity and education about the new import requirements, and achieve a higher level of U.S. food security without disrupting trade. I am satisfied that this policy guide presents a realistic strategy for facilitating the flow of this essential commerce, as well as holiday food packages, while countering the threat of terrorism."

In the spirit of Commissioner McClellan's intentions, the following comments are offered in the hopes of working with the FDA on continued protection of the American food supply in a manner intended not to disrupt the free flow of unadulterated and safe food products into the United States. Collectively, member businesses of the American Free Trade Association are committed to delivering only unadulterated and approved product into the U.S. marketplace and are willing to do everything they are able to do to evidence the safety of their goods to the FDA.

I. There is every reason to believe that domestic manufacturers will utilize the right to selectively disseminate registration numbers as a means to monopolistically control product resale and global distribution.

For literally centuries, manufacturers have battled against parallel importation as they have sought to protect the domestic marketplace for exclusive product distribution and price control. Nevertheless, to date, all such efforts have failed --- largely because both the U.S. Supreme Court and the Congress have denied manufacturers the express means to prevent such desirable competition.

As background, parallel Goods are genuine consumer products of all genres, such as fragrances, 35 mm cameras, electronic products, food and watches which are imported, distributed and/or sold in the secondary marketplace by independent American businesses rather than by "authorized" U.S. dealers. The parallel marketplace exists primarily because the manufacturers, for reasons of their own, seek significantly higher prices for their products in the United States than elsewhere in the world. They often do this by creating wholly-owned or controlled subsidiaries in this country, designating those companies as the exclusive "authorized" importers and distributors for their products here, and refusing to sell to retailers and distributors who will not maintain the higher prices for the products.

The obvious result in a free enterprise, free trade market is that independent American businesses can purchase the same products overseas at the less expensive world price, often directly from the manufacturers' "authorized" distributors abroad. These same businesses often purchase the genuine products domestically, either from authorized distributors or from the manufacturers themselves. The foreign manufacturers' price differential for the U.S. market is often so great that, even after paying shipping costs and U.S. Customs duties, the parallel importer can offer the identical articles for twenty to forty percent less than the U.S. "authorized" distributor.

The result is a saving to American consumers amounting to billions of dollars a year. Another result is the availability of popular products to a much wider spectrum of Americans who do not live in the large cities where the exclusive authorized stores are generally located. The parallel trade has also served as an independent bulwark against unrestrained increases on the domestic price of brand name consumer goods as compared to prices available worldwide.

The parallel marketplace thrives because it is a legal and important way for consumers of all income levels and locations to avail themselves of brand name merchandise. Parallel marketers are legitimate businessmen working against the counterfeiting and infringement of intellectual property rights because their own livelihood depends upon the integrity and recognition of valid and genuine trademarks. The Supreme Court has twice upheld the validity and importance of the parallel marketplace. This is because the economic theories of supply and demand and of the free marketplace mandate that genuine brand name merchandise be made available to all consumers without discrimination and without retaliation against distributors.

The first published conflict between a manufacturer and a parallel importer goes back to 1886 in Appollinaris Co. Ltd. v. Scherer, 27 F 18 (CC SDNY 1886). In that case, the Circuit Court for the Southern District of New York declined to enjoin an early parallel importer from importing goods bearing a mark legitimately affixed by a foreign manufacturer. Since 1886, efforts to limit or eliminate parallel market competition have been mounted in Congress, the Courts and the Executive branch under virtually every conceivable law, including our customs laws, trademark laws, copyright laws, patent laws, the uniform commercial code and, antitrust laws. But, these efforts have failed. As recently as 1998, by the Supreme Court's decision in Quality King v. L'Anza International Research (holding that manufacturers may not rely upon the U.S. copyright law to bar reimportation of domestically manufactured products), or in 1999 with the final Customs regulations implementing the decision in the *Lever Brothers* case (parallel imports will be allowed even for products determined to be materially different from those authorized for U.S. distribution so long as they are labeled to identify that they are unauthorized merchandise), manufacturers have been stopped in their attempts to quash this desired, legitimate business practice of supplying consumers with more -- and less-expensive-- branded merchandise.

In 1998, - not long after the Supreme Court rejected the copyright theory for eliminating the parallel market in its holding in Quality King v. L'Anza – the battle shifted to the Congress with the introduction of H.R. 3891 the "Anticounterfeiting Act of 1998." This bill would have effectively wiped

out the secondary marketplace-- although, on its surface, it did not appear to contradict the Supreme Court's rulings or the historic support of the parallel market. H.R. 3891 failed in 1998, and, so, in 1999 it resurfaced as H.R. 2100 --- legislation that, again, did not appear to obviously eradicate an industry desired by the American consumer and legitimized by America's court systems and administrative bodies but nevertheless would have accomplished exactly that. This legislation also failed to even be heard before the full House.

Like these congressional efforts to stop the parallel market, the BioTerrorism Preparedness Act of 2002 (the "Act") does not, on its face, eliminate parallel importation thereby confirming Congress' desire to maintain the legitimate form of competition provided by this industry. However, because the BTA Regulations implemented by the FDA require that Prior Notice submissions include manufacturer's registration numbers, which will not be voluntarily provided to anyone other than those importers controlled directly by the manufacturers, eradication of the parallel marketplace will be the single most obvious effect. For the FDA to provide domestic manufacturers with a right to control product distribution of brand name food items in this manner when Congress and the Supreme Court have both held such a right to be an impermissible expansion of U.S. law is simply indefensible. The Agency has no authority to promulgate such a regulation and the American public will not support it.

Fortunately, the American marketplace favors free competition. As a result, AFTA member businesses are often in direct competition with U.S. manufacturers, with whom they may have no relationship. Solely as a result of this legitimate but unwanted competition, domestic manufacturers are unlikely to provide facility registration numbers to importers with whom they have no direct relationship, especially when there is no incentive to do so. Without a requirement for this type of disclosure or other means of obtaining this information, under the existing Prior Notice BTA Regulations, domestically manufactured products produced by registered manufacturing facilities will be denied entry into the national marketplace. As a result, this vital form of competition will be eliminated. The granting of absolute control of distribution to manufacturers is not part of the legislative scheme, nor is it needed to fulfill the purposes of the Bioterrorism Act.

In its comments to the proposed regulations, the National Association for the Specialty Food Trade, Inc. understood that the FDA could not, on the one hand, claim loyalty to free trade and, on the other, broaden the authorities provided to it under the Act contrary to those dictums. "When the United States is negotiating free trade agreements such as a Free Trade Area of the Americas and a global trade liberalization package under the auspices of the World Trade Organization – all of which will contain immense trade benefits for some U.S. food companies – it would be more useful to construe faithfully but narrowly the prior notice requirement of the Bioterrorism Act." AFTA respectfully echoes these comments and urges the FDA to amend the BTA Regulations in order to avoid an even implied hypocrisy. To broaden the prior notice requirements of Act by requiring importers to provide unavailable registration numbers of unaffiliated parties as a condition of importation defies the commitment to unfettered trade proclaimed by Commissioner McClellan on December 11, 2003.

II. The Act Does Not Require Registration Numbers on Prior Notice Submissions

Section 307 of the Act requires identification of certain supply chain partners on the Prior Notice to ensure that the FDA has the information necessary to inspect those shipments that may pose a health or safety risk to the American consumer. Specifically, Section 307 states the following:

> SEC. 307. PRIOR NOTICE OF IMPORTED FOOD SHIPMENTS. (a) In General.--Section 801 of the Federal Food, Drug, and Cosmetic Act, as amended by section 305(c) of this Act, is amended by adding at the end the following subsection:
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> ``(m)(1) <<NOTE: Regulations.>> In the case of an article of food that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; if known within the specified period of time that notice is required to be provided, the grower of the article; the country from which the article originates; the country from which the article is shipped; and the anticipated port of entry for the article. An article of food imported or offered for import without submission of such notice in accordance with the requirements under this paragraph shall be refused admission into the United States. Nothing in this section may be construed as a limitation on the port of entry for an article of food. (http://www.fda.gov/oc/bioterrorism/PL107-188.html#title3)

AFTA members are able and eager to provide the FDA with all of the information required under Section 307 of the Act. And, as set forth therein, should they be unable to do so, they accept that entry of that particular food article will be denied. However, the FDA by virtue of the BTA Regulations has augmented Section 307 to require not only supply chain party identification but also the registration number of the manufacturer and the shipper. While the latter requirement is easily met, for the reasons stated herein, the manufacturer's registration number will be difficult, if not impossible, to obtain by any party not directly affiliated with that facility. A domestic manufacturer will not willingly disclose such information to a known competitor. The result of this selective dissemination will be to provide domestic manufacturer with the exclusive means to control product distribution and resale price. This is not only unsupported under existing U.S. law but violates the very tenets of the freely competitive American marketplace.

III. Requiring registration numbers of manufacturers on Prior Notices does nothing to protect the American food supply

Congress has adopted a wide-range of bills that thoughtfully and effectively protect consumers from defective and unsafe products. The labeling and branding of foreign and domestic merchandise is regulated under the *Federal Food Drug and Cosmetic Act*. See 21 U.S.C. 331 (misbranding of any food, drug, medicine and liquor); 334 (food, drug, device or cosmetic), 342 and 342 (food); 350a (infant formulation); 351 and 352 (drugs and devices) and 361 and 362 (cosmetics), as well as the *Federal Meat Inspection Act* (21 USC 601, et. seq); and consumers are protected against deception, confusion and unfair competition as a result of *The Lanham Act* (15 USC 1051, et. seq.); *The Copyright Act* (17 USC

101, et. seq.); *The Tariff Act* (19 USC 1526) and *Anticounterfeiting Consumer Protection Act of 1996* (15 USC 1116-17; 18 USC 2320).

In addition to the laws described above, there are several laws that restrict parallel imports of specific products (*e.g.,* prescription pharmaceuticals and tobacco products) or that can be invoked to exclude parallel imports (*e.g.,* Section 337). For example, the Prescription Drug Marketing Act of 1987 prohibits the reimportation of prescription drugs except by the manufacturer.[1] In passing this statute, Congress found that the importation of drugs prevented effective control and knowledge of the true sources of prescription drugs, and that reimported drugs are a public health and safely risk. Previously exported U.S.-manufactured tobacco products may only be imported into the United States to the original manufacturer or an export warehouse proprietor with the authorization of the original manufacturer.[2] In addition, cigarettes bearing a registered U.S. trademark may only be imported into the United States if the owner of such U.S. trademark, or the owner's authorized representative, has consented to the importation.[3]

The legislative history of all of this legislation clearly reveals an intention to protect American consumers from harm and a genuine concern for their well- being as well as Congress' intent to carefully regulate parallel goods to ensure the safety of the American marketplace without impeding legitimate and necessary trade. The BTA Regulations, however, do not represent an ongoing effort to protect the American consumer. There is no review of registered facilities to ensure that they are bringing safe and secure products into the United States and even a terrorist-related manufacturer may easily have its facility registered under these rules.

Nevertheless, AFTA members are willing to assist the FDA by reasonable means to ensure that the products they import present no risk to the health or safety of American consumers. To this end, if the lack of a registration number on a Prior Notice necessarily results in inspection of a food shipment to ensure its safety, this is an acceptable consequence for the industry. The objective of the FDA, whether under the BTA Regulations or otherwise, should be to ensure the safety of the American food supply. Requiring manufacturer registration numbers on Prior Notices submitted by unrelated parties does nothing to further this goal, since registered facilities may, in fact, be shipping unsafe products to the United States. However, working with traders to facilitate increased inspections should be a mutually undertaken responsibility and one which members of the American Free Trade Association are ready to accept. Moreover, parallel market traders often import the same products from the same sources, are represent legitimate businesses that can be evaluated for inspection or automatic detention purposes in

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[1] 21 U.S.C. 381(d)(1) & (2).

[2] *See* 26 U.S.C. 5754(a) and 5704(d) (as amended, Dec. 2000).

[3] *See* 19 U.S.C. 1202 (as amended by P.L. 106-476, Sec. 4004 (Nov. 9, 2000)). The Senate Report language regarding this amendment included the following statement: "In this regard, however, it should be noted that the gray market restriction provisions of this bill are crafted for the special circumstances of tobacco. This provision, however, is not intended to alter current policies with regard to other gray-market goods." 106 S.R. 476 at 92 (Oct. 12, 2000).

the same way that the FDA measures other importers. We urge that FDA take these circumstances into account in determining how to use its resources (and that of Customs & Border Protection) to most efficiently and effectively inspect for bioterrorism issues.

In this regard, the FDA is respectfully reminded that the Congress specifically charged the Agency with the burden of increasing inspections of food shipments as a part of the Act. Section 302 of the Act specifically states that "``(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food." And, in fact, the FDA was initially appropriated $100,000,00 by Congress to accomplish this feat. AFTA members will work with the FDA to facilitate such inspections and, again, these traders recognize that lack of a manufacturer's registration number on a Prior Notice may be deemed sufficient reason to instigate such an examination. However, while bearing the burden of a port inspection may be a reasonable consequence of overtly competing with domestic manufacturers, being denied entry of lawfully made and otherwise admissible articles is not.

IV. The Permissibility of U.S. Goods Returned under both CBP and FDA Regulations Requires Flexibility and Discretionary Enforcement

Interestingly, although requiring manufacturers' registration numbers on Prior Notices may very well result in the elimination of legal parallel market trade and will prevent importation of lawfully domestically manufactured goods, neither the Bureau of Customs and Border Protection (CBP) nor the FDA expressly prohibits this merchandise from entry into the domestic marketplace.

The only "condition" imposed by CBP on U.S. Goods Returned is one which is determinative of whether duty will be owed upon reimportation. Goods, if manufactured in the US, exported, and subsequently returned, may be returned to the US free of duty, provided they were not advanced in value or improved in condition by any process or manufacture or other means while in a foreign country. In most other circumstances, while reimportation of domestically manufactured products will be allowed, duty may be assessed against such imports. Unless the shipment consists of otherwise prohibited merchandise, at no time and under no conditions does CBP outrightly prohibit entry of U.S. Goods Returned due solely to the fact that they are being imported by someone other than the original manufacturer.

Similarly, the FDA itself has no regulation or rule that expressly prohibits U.S. Goods Returned. Even under the Act, so long as the regulated products are listed, are from registered establishments, are labeled correctly and otherwise meet all FDA regulations, they may be imported by any party regardless of relationship to the original domestic manufacturer. This is not a position conspicuously contradicted by the BTA Regulations.

While the BTA Regulations clearly indicate that the manufacturer's registration number is required on the Prior Notice, even for U.S. Goods Returned, they do not expressly indicate that refusal will result in the event such a number is not provided. Rather, Section 1.285(a) of the BTA Regulations

only indicates that goods arriving from an unregistered *foreign* facility will be subject to refusal as will goods arriving with a Prior Notice indicating an inaccurate registration number for a *foreign* facility. In more general terms, under Section 1.283(a)(ii), the BTA Regulations also subject food arriving with an "inaccurate" Prior Notice to the same possibility of refusal upon arrival. However, there is nothing inaccurate about an importer not including a registration number on its Prior Notice for a manufacturer in connection with which it has no knowledge of the correct registration number. And, because the BTA Regulations, specifically discuss only that an inaccurate registration number for a *foreign* facility is an obvious violation of the Regulations, it again must be assumed that even the FDA is willing to concede that there may be circumstances under which Prior Notices may lack registration numbers for domestic manufacturers --- even those that are duly registered --- without subjecting the applicable food article to automatic refusal. Importantly, literally the language of the BTA Regulations indicates that food arriving with inaccurate Prior Notice will be "subject to" (but not guaranteed) refusal. This certainly suggests flexibility and/or discretionary enforcement.

The FDA's discretionary authority, especially in connection with whether or not to require manufacturer's registration numbers on Prior Notices, is again plainly evidenced by the fact that the BTA Regulations permit an importer not to include such a number in the event a personal shipment --- a gift – is sent form one individual to another (Section 1.2819a)(6)). In such a case the Prior Notice is permitted to indicate the name and address of the manufacturer as it appears on the label. Why, then, should the FDA not utilize such discretionary authority in the case of permitted and lawful U.S. Goods Returned? The FDA's obligation under the Act to review registration of the manufacturer of an imported gift is no less than its obligation to review that information for any other item. Accordingly, if an exception can be made in one instance, it must be made in the other – especially when to insist otherwise is to jeopardize an entire industry in a manner unsupported by current U.S. law.

V. Difficulties in Enforcing the Registration Requirements Should Not Be The Basis To Deny Lawful Import

In its response to the comments received after publication of the proposed Prior Notice rules in February 2003, the FDA indicated that registration numbers must be provided on Prior Notice in order to accurately identify the manufacturer for verification of compliance with the registration requirements of the BTA. The following statement was made by the FDA in response to a comment submitted indicating that the Prior Notice submitter may not know the necessary registration number and accordingly the FDA should be able to confirm the registration numbers within its own internal system:

> Registration is designed to work in concert with prior notice at the border, as reflected in new section 801(l) of the FD&C Act, which provides that food from facilities that must register may not be admitted into distribution for consumption in the United States unless the relevant facilities have been registered. To enforce section 801(l) of the FD&C Act as intended by Congress, FDA has determined that it must review registration status of manufacturers and shippers as part of prior notice.

AFTA members understand and concur with the foregoing statement. But the obligation to verify that the manufacturer of a food article entered for consumption into the United States is registered

is an obligation imposed upon the FDA by Congress under the Act, not upon the importer. For the FDA to shift its burden to importers who are not related to the facilities required to be registered is, at the very least, unjust and certainly was not the intent of Congress.

Lack of a manufacturer's registration number on a Prior Notice may not reflect anything other than the fact that the importer had no means of verifying with the manufacturer its correct registration number. Instead, that importer elected to leave that portion of the Prior Notice empty in lieu of recording an improper number, which would certainly be more disruptive to international trade and lead to undesirable and unnecessary delays at the ports.

If the Prior Notice contains information sufficient to identify the manufacturer and the shipper, and the FDA (via its own words) has confirmed its obligation to review the registration status of those facilities prior to importation or acceptance of the Prior Notice, then, by all means, the FDA should do so. But such a review must not be premised upon the importer providing the FDA with registration numbers it has no means of obtaining. To insist upon such a requirement would effectively cede the responsibility placed upon the Agency onto the shoulders of law-abiding importers with no means to comply. The FDA has the ability and access to the information necessary to verify registration status of domestic manufacturers; unaffiliated importers do not.

VI. No other FDA requirements for listing and/or registration deny importation of lawful domestically manufactured products

The FDA requires product listing and manufacturer registration for medical devices and pharmaceuticals. It cannot be debated that these products are as potentially dangerous to American consumers as are food items. Nevertheless, the FDA has not intentionally taken steps to deny legitimate importation of these items in the conspicuous manner they have done in connection with food articles.

In connection with drug listings and registrations, FDA regulations provide the following:

> §207.37 Inspection of registrations and drug listings. (a) A copy of the Form FDA 2656 (Registration of Drug Establishment) filed by the registrant will be available for inspection in accordance with section 510(f) of the act, at the Drug Listing Branch (HFD-334), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, there will be available for inspection at each of the FDA district offices the same information concerning firms within the geographical area of each district office. Upon request and receipt of a self-addressed stamped envelope, the Drug Listing Branch, Center for Drug Evaluation and Research or appropriate FDA district office will verify registration number or provide the location of a registered establishment.
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> (1) The following types of information submitted under the drug listing requirements will be available for public disclosure when compiled: (i) A list of all drug products. (ii) A list of all drug products arranged by labeled indications or pharmacological category. (iii) A list of all drug products arranged by manufacturer. (iv) A list of a drug product's active ingredients. (v) A list of drug products newly marketed or for which marketing is resumed. (vi) A list of drug products discontinued. (vii) Labeling. (viii) Advertising. (ix) Information that has become a matter of public knowledge. (x) A list of drug products containing a particular active ingredient. (xi) A list of all code imprints.

> (2) The following types of information submitted in accordance with the drug listing requirements will not be available for public disclosure (except that any of the information will be available for public disclosure if it has become a matter of public knowledge or if FDA finds that confidentiality would be inconsistent with protection of the public health): (i) Any information submitted as the basis upon which it has been determined that a particular drug product is not subject to section 505, 506, 507, or 512 of the act. (ii) A list of a drug product's inactive ingredients. (iii) A list of drugs containing a particular inactive ingredient.

Notwithstanding the availability to interested parties of information necessary to confirm whether or not a particular pharmaceutical may be lawfully distributed in the United States, current U.S. law prohibits reimportation of human pharmaceuticals. The fact that certain listing information for these articles is fully obtainable by the public does not mitigate this outright prohibition. Neither the BTA Regulations, or any other FDA regulations, however, expressly prohibit reimportation of food articles, nor should they. Therefore, it makes no sense for the FDA to deny confirmation, even if only through internal channels at the point of Prior Notice examination, that a described manufacturing facility is, indeed, registered as a means of curing an otherwise deficient Prior Notice. For the FDA to make such information public for prohibited merchandise such as reimported pharmaceuticals but to not permit even confirmation of permissible import for lawfully shipped articles is, respectfully, nonsensical.

The medical device listing regulations specifically provide the following:

> (b)(1) The following information filed under the device listing requirements will be available for public disclosure: (i) Each form FD-2892 submitted; (ii) All labels submitted; (iii) All labeling submitted; (iv) All advertisements submitted; (v) All data or information that has already become a matter of public knowledge. (2) Requests for device listing information identified in paragraph (b)(1) of this section should be directed to the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, Department of Health and Human Services, 1390 Piccard Dr., Rockville, MD 20850. (3) Requests for device listing information not identified in paragraph (b)(1) of this section shall be submitted and handled in accordance with part 20 of this chapter.

Although medical device listing numbers are not publicly available through the FDA website, they are obtainable through Freedom of Information Act (FOIA) Requests and, accordingly, importers of duly listed devices may verify that the goods intended for import are approved for distribution in the United States and, in fact, may properly enter these products into the U.S. In connection with food articles, AFTA is requesting nothing more. That is, importers of food articles only ask that the FDA provide the means for importation of products manufactured by registered facilities.

While AFTA understands and appreciates that the Act itself prohibits disclosure of "registration information" in an effort to protect confidential business information, requiring registration numbers on Prior Notices does not apply this restriction against disclosure in the intended manner. The FDA would have difficulties supporting such a requirement in light of the fact that even for prohibited merchandise it readily provides "confidential" information to parties needing or wanting to know whether a particular product is approved for distribution in the United States. There is no basis to deny access to information that will permit importation of approved articles into the United States, especially when importation of those goods is permitted under U.S. law.

CONCLUSION

The domestic economy has long benefited from the competition provided by the parallel marketplace and U.S. law supports its operation. American consumers deserve the opportunity to find genuine, domestically manufactured food items at a broad range of locations and to "shop around" for the best deals on those products. Existing law strikes a delicate balance between the rights of manufacturers to control the distribution of their products with the rights of the government to protect American consumers and the rights of consumers, themselves, to benefit from a freely competitive marketplace. This balance, maintained through literally centuries of ongoing battles that have resulted in U.S. law continually supporting regulated parallel importation and distribution, provides financial rewards throughout the domestic marketplace that should not be eliminated as a result of BTA Regulations that inexplicably broaden Congress' objective by implementing rules that will eliminate a much-needed domestic industry.

In their present form, the BTA Regulations will severely threaten if not outrightly destroy the existing trade in re-imported domestically manufactured food products. Requiring importers to provide unrelated manufacturer's registration numbers on the Prior Notice would provide unprecedented and unfettered authority to prevent importation of products by anyone other than the manufacturer itself, or its authorized distributor, and this is a restriction of trade that is unsupported by U.S. law. Since the FDA has elected not to implement regulations conditioning facility registration on safety or security related criteria, the elimination, even if unintentional, of the parallel import industry will, in no way, augment the safety benefits gleaned from the Act.

AFTA members are eager to work with the FDA on finding a solution to this issue and they recognize the difficulties the FDA faces in crafting regulations that protect America's food supply without hindering the dynamics of an open and free marketplace. These businesses are law-abiding, tax-paying traders and merely request that the FDA consider that the parallel market industry is legal in this country, supported by recent judicial and legislative actions and offers much needed competition to American consumers struggling to find reasonably priced consumer goods. The BTA Regulations should be amended to permit the continued operation of the secondary marketplace and AFTA looks forward to continuing dialogue with the Agency to further this objective.

In that regard, it is respectfully requested that the FDA welcome representatives of AFTA, and similarly concerned associations, during the months between the closure of this first comment period and the next one commencing in Spring 2004 in the spirit of continued outreach and uninterrupted progress toward final rulemaking. It is critical to thousands of U.S. businesses, the millions of their employees and to American consumers that the parallel marketplace be maintained. Because U.S. law supports the continued reimportation of domestically manufactured food items and because Congress implied nothing else by its passage of the Act, it is respectfully asked that we work together to ensure that the final BTA Regulations do not even inadvertently have the opposite effect.

It is respectfully requested that the undersigned or Lauren Perez of this office be contacted directly upon the FDA's review of the foregoing comments in order that further discussions and meetings may be scheduled.

Respectfully submitted,

By: _____
Gilbert Lee Sandler
General Counsel

cc: AFTA Members and Board of Directors
Lauren V. Perez

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