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Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION

This citizen petition is submitted pursuant to section 801(n)(1), as amended, of the Federal Food, Drug, and Cosmetic Act (FDC Act), and 21 C.F.R. §§ 10.25(a), 10.30, and 10.40. Petitioners request that the Commissioner of Food and Drugs conduct a notice-and-comment rulemaking in order to implement the Food and Drug Administration's (FDA) new authority to require the marking of food refused admission into the United States (hereafter, the "marking provision"), contained in section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P.L. No. 107-188 (hereafter, the "Bioterrorism Act"). Informal comments of agency personnel indicate that FDA plans to implement the marking provision through the issuance of a guidance document. Petitioners object to such a procedure.

A. Action Requested

Petitioners request that FDA conduct a notice-and-comment rulemaking in order to implement the marking provision of the Bioterrorism Act. Petitioners respectfully submit that implementation of the marking provision through issuance of a guidance document would fail to meet requirements of the Administrative Procedure Act (APA), 5 U.S.C. § 553, and would restrict appropriate public input.

B. Statement of Grounds

Background

1. Petitioners

Petitioners are seven food industry trade associations dedicated to enhancing the security of the U.S. food supply. The Petitioners are the American Spice Trade Association, the Association of Food Industries, the Cheese Importers Association of America, the Cocoa Merchants' Association of America, the International Dairy Foods Association, the National Fisheries Institute, and the National Food Processors Association:

- The American Spice Trade Association (ASTA), a non-profit trade association, has represented the spice industry for over 95 years. The membership is comprised of growers, shippers, importers, processors/blenders, and manufacturers whose imports are valued at over $600 million.

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ASTA's mission is to advance, preserve, and promote the spice industry. ASTA's mission is to advance, preserve and promote the spice industry consistent with the public interest.

- The Association of Food Industries (AFI) is a trade association serving the food import trade. AFI is committed to developing programs that facilitate the business of its member companies, encourage free and fair trade, and foster compliance with United States laws and regulations for the food industry. AFI members import goods worth approximately $1 billion each year.

- The Cheese Importers Association of America is a non-profit trade association formed more than fifty years ago whose membership comprises the vast majority of the firms engaged in the business of importing, selling, promoting, and distributing cheese, butter and other edible dairy products in the United States. Each year, member firms import cheese and dairy products valued at $1 billion.

- The Cocoa Merchants' Association of America, Inc. is a non-profit trade organization founded in 1924 and groups as its Regular Members all major importing dealers of cocoa beans and cocoa products. The total cocoa import value in 2001 was $1.015 billion. This number includes imported "industrial" chocolate (couverture) and confectioner coating (compound).

- The International Dairy Foods Association (IDFA) is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA's 500-plus members range from large multi-plant corporations to single-plant operations, and represent more than 85% of the total volume of milk, cultured products, cheese, and ice cream and frozen desserts produced and marketed in the United States – an estimated $70 billion a year industry.

- The National Fisheries Institute (NFI) is the leading trade association for the fish and seafood industry, and represents a wide spectrum of firms, from small family-owned businesses to large multinational corporations. NFI is committed to helping its members succeed in the global seafood marketplace. Seafood imports into the United States are valued at approximately $9.9 billion.

- The National Food Processors Association (NFPA) is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters, food security, and consumer affairs. NFPA's three scientific centers, its scientists, and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications, and crisis management support for the association's U.S. and international members.

2. Marking Provision of the Bioterrorism Act

The marking provision of the Bioterrorism Act provides FDA with the discretionary authority to require the marking of food that has been refused admission into the United States with a label bearing the statement: "UNITED STATES: REFUSED ENTRY." 21 U.S.C. § 381(n)(1), as amended. The new law also specifies that a food will be deemed misbranded if: (i) the food has been refused admission and fails to bear the required label; (ii) FDA has determined that the food presents a threat of serious adverse health consequences or death to humans or animals; and (iii) FDA has notified the food's owner of the label requirement and the threat posed by the food. 21 U.S.C. § 343(v), as amended.

Prior to the passage of the Bioterrorism Act, FDA considered the establishment of requirements for marking imported food that has been refused entry into the United States. Indeed, in January 2001, the agency issued a proposed rule that, among other things, would have required importers whose food has been refused entry into the United States for safety reasons, and who wished to re-export the food, to mark the product with the statement: "UNITED STATES REFUSED ENTRY." 66 Fed. Reg. 6,502 (January 22, 2001). In the proposed rule, the agency solicited comments on several issues, including what the label would look like and where it would be placed. Id. at 6,504. The agency also held two public meetings to gather input and information from stakeholders. 65 Fed. Reg. 3,461 (January 21, 2000). In August 2002, following the passage of the Bioterrorism Act, FDA withdrew the proposed rule. 67 Fed. Reg. 54,138 (August 21, 2002).

As set out below, in order to properly implement the marking provision of the Bioterrorism Act, FDA must engage in action that, pursuant to the APA, only may be conducted through a notice-and-comment rulemaking. In addition, because the marking requirement is a form of compelled speech, the agency must exercise particular vigilance to ensure the new requirements comport fully with the First Amendment and the law as laid down in Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York, 447 U.S. 557 (1980) and U.S. v. United Foods, Inc., 553 U.S. 405 (2001). By conducting a notice-and-comment rulemaking – and availing itself of the record that process generates – FDA will be able to assure that the final marking requirements, when implemented and applied, pass constitutional muster.

Pursuant to the APA, FDA is Required to Conduct a Notice-and-Comment Rulemaking

Under the APA, when an agency issues a "rule," it is required to publish a general notice of proposed rulemaking in the Federal Register, and to provide an opportunity for stakeholders to participate in the process. 5 U.S.C. § 553. The APA defines a "rule" as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. . . ." 5 U.S.C. § 551(4). The APA provides narrow exceptions to the notice-and-comment requirement for "interpretive rules," "general statements of policy," or

"rules of agency organization, procedure, or practice." 5 U.S.C. § 553(3)(A). A rule that does not fall within one of these three exceptions is a "legislative" or "substantive" rule, which must be promulgated through notice-and-comment rulemaking. See Community Nutrition Institute v. FDA, 818 F.2d 943, 946 (D.C. Cir. 1987); Chisholm v. FCC, 538 F.2d 349, 393 (D.C. Cir. 1976).

Any statement issued by FDA to implement the marking requirement clearly would constitute a "legislative rule," and, as such, would be subject to the APA's notice-and-comment rulemaking requirement. In defining a "legislative rule," the D.C. Circuit Court has said that "if a statement has a present-day effect, it is legislative. Mere pronouncements of what the agency intends, whether for the present or for the future, which do not have a binding effect, are properly classified as interpretive rules." Community Nutrition, 818 F.2d at 946; see also Syncor Intern. Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997); U.S. Telephone Ass'n v. FCC, 28 F.3d 1232, 1234 (D.C. Cir. 1994). "[A] 'general statement of policy' is one that does not impose any rights or obligations." Community Nutrition, 818 F.2d at 946 (quoting American Bus Ass'n v. U.S., 627 F.2d 525, 529 (D.C. Cir. 1980)). A rule that satisfies the procedural exception covers agency actions that do not themselves alter the rights or interests of parties. Hurson v. Glickman, 229 F.3d 277, 280 (D.C. Cir. 2000).

In Community Nutrition, the D.C. Circuit Court found the agency pronouncement in question (the issuance of "action levels" for aflatoxins in corn) to be a "substantive" (legislative) rule, and, therefore, subject to the APA's notice-and-comment rulemaking requirement, because the agency's action would have a "present, binding effect" on both the regulated industry and the agency itself. Id. at 947. In making this determination, the court largely focused on the agency's use of "mandatory, definitive language," e.g., the establishment of specific action levels defining acceptable amounts of aflatoxins. Id. at 947-948 ("[A]ction levels are not musings about what the FDA might do in the future but rather they set a precise level of aflatoxin contamination that FDA has presently deemed permissible. Action levels inform food producers what this level is; indeed, that is their very purpose.")

Given the lack of specificity in the Bioterrorism Act's marking provision, FDA could not implement it effectively without using "mandatory, definitive language" that has a "present, binding effect" and that imposes "rights or obligations" on food importers. The marking provision is not self-effectuating. To the contrary, in many areas, FDA must use its discretionary authority to fill in substantive "gaps" left by the statute. Filling in these "gaps" requires more than the issuance of a general policy statement, a rule of agency procedure, or a mere interpretation of the statute.

The most significant substantive "gap" in the marking provision is that it does not specify the circumstances under which a mark will be required. When FDA proposed a marking requirement in January 2001, the agency stated that the requirement would be imposed on products that had been refused entry for safety reasons. 66 Fed. Reg. at 6,504. FDA further clarified that "safety reasons means that consuming the imported food could adversely affect a person's health." Id. The agency

also stated that it would not require a marking for an import that had been refused entry for non-safety reasons, such as being labeled in a foreign language. Id. In contrast, the Bioterrorism Act's marking provision simply authorizes FDA to require that rejected imports be marked, without instructing the agency as to when such a mark should be required. Clearly, this matter can be addressed only through the issuance of a substantive, definitive statement that binds both FDA and industry.

Another substantive "gap" that the agency must "fill in" is information regarding the mark's appearance. Indeed, the marking provision does not address how the mark should look, e.g., the size of the mark, and how it might vary due to the variety of food packages and product sizes. Likewise, the provision does not addresss where the mark should be applied. Although the marking provision's legislative history indicates Congress' intent that the "outermost container" – not the immediate container – be marked (see 148 Cong. Rec. H2857 (daily ed. May 22, 2002) (statement of Rep. Shimkus)), the provision itself does not deal with this issue, nor does it address those circumstances where it would be impossible to place the mark on a packing container, e.g., bulk agricultural commodities. Again, these are matters that FDA must address through notice-and-comment rulemaking and the promulgation of a legislative rule.

As noted above, FDA previously initiated a rulemaking and conducted two public meetings on the very issue of marking food that has been refused entry into the United States. Indeed, the preamble to FDA's January 2001proposed rule demonstrated the agency's struggle with many of the same substantive "gaps" that now must be "filled in," e.g., when to require the mark, what the mark should look like, where it should be placed. Thus, the agency historically has understood the complexity of implementing a food marking provision and the necessity of gathering public input through a notice-and-comment rulemaking. Moreover, the Bioterrorism Act's legislative history demonstrates Congress' intent that FDA, in conjunction with U.S. Customs, develop regulations to implement the marking provision. See 148 Cong. Rec. H2857 (daily ed. May 22, 2002) (statement of Rep. Shimkus).

Clearly, it is incumbent upon FDA to conduct a notice-and-comment rulemaking in order to implement the marking provision of the Bioterrorism Act. Failure to do so would be inconsistent with the requirements of the APA.

FDA Should Conduct a Rulemaking in Order to Assure Protection of First Amendment Rights

1. A Marking Requirement Is A Form Of Compelled Speech That Could Impinge Upon First Amendment Rights

As is well known and often repeated, the First Amendment to the United States Constitution protects commercial speech from unwarranted government regulation. Central Hudson, 447 U.S. at 561. Just as the First Amendment may prevent the government from prohibiting speech, the First Amendment also may prevent the government from compelling individuals to make certain speech. United Foods, 121 S. Ct. at 2338. Indeed, the courts have established that compelled product or package labeling, including mandated disclaimers and compulsory statements, constitutes compelled commercial speech, subject to First Amendment protection. International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 71-72 (2d Cir. 1996). Unjustified or unduly burdensome disclosure requirements may offend the First Amendment. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985). Disclosure requirements must be "reasonably related" to the government's interests in preventing deception. Id. See also United Foods, 121 S. Ct. at 2341 (compelled expression is unconstitutional if it is not necessary to prevent consumers from being deceived).

The Bioterrorism Act's marking provision, when implemented, is a form of compelled commercial speech that implicates the First Amendment rights of importers. The marking will force an importer to make a derogatory statement about its own product. Any FDA imposition of a marking requirement must comport with the test set out in the seminal Central Hudson case, 477 U.S. at 557, and amplified in Western States, 122 S. Ct. at 1504.

Under Central Hudson, a government restriction upon commercial speech is constitutional if, as a threshold matter, the commercial speech concerns unlawful activity or is misleading. Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. The First Amendment does not protect such speech. However, if the speech concerns lawful activity and is not misleading, a court must then evaluate whether the asserted governmental interest in the restriction is substantial. Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. If the government's interest is substantial, a court next determines "whether the regulation directly advances the governmental interest asserted." Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. Finally, the court determines whether the government restriction is "more extensive than is necessary to serve that interest." Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. In order for the restriction on speech to be constitutional, each of these three questions must be answered in the affirmative.

The burdens Central Hudson and its progeny impose on the government are not "mere speculation or conjecture." Edenfield v. Fane, 507 U.S. 761, 770-71 (1993). "[A] governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites

are real and that its restriction will in fact alleviate them to a material degree." Edenfield v. Fane, 507 U.S. 761, 770-71 (1993). In the instant matter, it is particularly important that FDA proceed carefully, in light of the growing recognition that the agency's restrictions and policies have impinged upon and continue to burden First Amendment rights. Indeed, significant court losses and volumes of overly burdensome restrictions on speech have forced FDA to take the admirable first step of examining how all its policies, regulations, and guidances may violate the First Amendment. See, e.g., Request for Comment on First Amendment Issues, 67 Fed. Reg. 34,942 (May 16, 2002). The agency should not now compound its existing First Amendment issues by overreaching in its implementation of the marking provision.

Given that the marking provision could impinge upon importers' First Amendment rights, it is wholly fitting that the agency implement the requirement through rulemaking, rather than guidance. Rulemaking is a serious process that is appropriate for consideration of serious issues. Rulemaking allows the agency to solicit comments and develop a record on these issues. Matters as important as compelling entities to make derogatory statements concerning their own products should not be relegated to the informal guidance process. Proceeding through rulemaking will enable FDA to implement the marking provision in a constitutional manner.

2. Through Rulemaking, FDA Can Better Satisfy The Requirements of Central Hudson

Depending upon how FDA implements the marking requirement, the compelled disclosure could seriously harm importers without providing any increased protection to United States citizens from the potential risks of adulterated or misbranded products. Petitioners have suggestions that would satisfy the concerns that underlie the marking requirement, without unduly burdening importers. In a rulemaking, this information would come to light for the agency to consider and incorporate into an administrative record. As discussed below, rulemaking would generate evidence and raise significant practical issues that would bear upon whether FDA implements the marking requirement constitutionally under Central Hudson.

a. Is FDA's Asserted Interest In Compelling Speech Substantial?

In exercising its discretion to impose the marking requirement, FDA should clearly explain the substantial government interest it seeks to advance. Petitioners understand FDA's interest to extend only to halting the purported practice of "port shopping" (i.e., attempting to re-import refused product at another port). The rulemaking record may establish that this interest is not so substantial (Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566) that it can support a broad, burdensome, or routinely imposed marking requirement. Indeed, there is strong evidence that the fears of "port shopping" that underlie the marking requirement have little basis in fact. In a rulemaking, this information would come to light for the agency to consider. Such fact gathering

would assist FDA in articulating its substantial interest, thereby helping to assure that the final marking requirement rests upon solid constitutional footing.

b. Does The Marking Requirement Directly Advance FDA's Substantial Government Interest?

Assuming FDA can articulate a substantial interest in the marking requirement, under Central Hudson, the marking requirement still must directly advance that interest. Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. A compelled marking requirement that does not further the government's interest in protecting public health and safety in the United States will not survive constitutional challenge. See United Foods, 533 U.S. at 416; Zauderer, 471 U.S. at 651.

If FDA is to force importers to make derogatory statements about their own products, it will need a record demonstrating that this compelled speech will prevent refused product from re-entering the United States. Congress emphasized that FDA should not use the authority granted in the law "to require markings that are unlikely to be observed at import inspection." See 148 Cong. Rec. H2857 (daily ed. May 22, 2002) (statement of Rep. Shimkus). In a notice-and-comment rulemaking, FDA would be able to gather information on these issues and establish a record that demonstrates how the marking requirement will accomplish its intended purpose in a constitutional manner.

c. Is The Marking Requirement More Extensive Than Necessary?

Finally, the marking requirement, as implemented and applied, must be no more extensive than is necessary to protect public health and safety. See Western States, 122 S. Ct. at 1504; Central Hudson, 447 U.S. at 566. FDA may be especially vulnerable on this prong of the Central Hudson analysis. Requirements regarding the mark's appearance (e.g., its size, its proportion to the container on which it is affixed) and where it should be placed (e.g., the outside container versus the individual package) could enormously burden importers without providing any commensurate benefit to United States border protection. As noted above, the relevant legislative history indicates that Congress intended for the "outermost container" to be marked. 148 Cong. Rec. H2857 (daily ed. May 22, 2002) (statement of Rep. Shimkus). However, if, contrary to Congress' intent, FDA were to require that every shipping container be completely unloaded so that each individual package is marked, such a requirement likely would be far more extensive than is necessary to protect United States borders.

The marking requirement must be flexible, for there are certainly circumstances under which its imposition would be unconstitutionally burdensome. For instance, when refused product is loaded onto a cargo ship and plainly bound for a foreign port, e.g., in Asia or Europe, there simply is no risk of the product returning to the United States. It is far too costly for even an unscrupulous importer to attempt re-importation, for there are no profits to be gleaned that could possibly offset

the enormous cost of offloading the product in a distant foreign port and then attempting re-importation of the product into the United States. Requiring marking under such circumstances would be more extensive than is necessary to prevent re-importation, because no such risk exists.

Moreover, in implementing the marking provision, FDA should not be permitted to destroy the future marketability of the product outside of the United States borders. Even in countries where the product may be lawfully marketed, a bold and blanket "UNITED STATES REFUSED ENTRY" mark is highly prejudicial. The marking requirements must preserve the foreign marketing option for importers. See 148 Cong. Rec. H2857 (daily ed. May 22, 2002) (statement of Rep. Shimkus) ("The conferees do not intend for this [marking] authority to be used to ... inhibit the lawful marketing of a product in another country).

FDA's earlier proposed rule to implement a marking requirement recognized that blanket marking requirements are inappropriate. The agency sought comment on possible disclosures and other potential measures that would allow for conspicuous marking but still would preserve the refused product's foreign marketability. 66 Fed. Reg. at 6,504. If FDA's implementation of the marking provision does not preserve an importer's ability to lawfully market refused product in foreign countries, the requirement will be more burdensome than is necessary to protect United States borders and will not pass scrutiny under Central Hudson.

* * *

In closing, Petitioners wish to reiterate their commitment to continue working with FDA and U.S. Customs to stop unsafe food imports and unsavory importers. While the overall safety record of food imports is exemplary, one shipment of violative product is one too many. Petitioners want to assure that the U.S. food supply continues to be the safest and most bountiful, while also ensuring the existence of a fair and rational regulatory scheme for food importers. In this regard, Petitioners strongly urge FDA to implement the marking provision through a notice-and-comment rulemaking. As set out above, by engaging in a rulemaking, FDA will assure compliance with the APA's requirements and the First Amendment's commercial speech protections. Moreover, conducting a rulemaking will enable the agency to craft a marking regulation based on a well-developed record of input from all affected parties. As a result, the ultimate objective of the marking provision – enhancing the safety of the United States food supply – is much more likely to be achieved.

C. Environmental Impact

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30.

D. Economic Report

Petitioners will submit an economic analysis upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views upon which Petitioners rely, and that it includes representative data and information known to Petitioners, which are unfavorable to the petition.

Respectfully submitted,

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