



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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Dockets Management Branch (HFA-305)
Food & Drug Administration
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Re: [Docket No. 02N-0278], Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5429-68 (February 3, 2003)

These comments are submitted on behalf of the Consumer Healthcare Products Association¹ in response to the proposed regulations published in the February 3rd *Federal Register* Notice. [Docket No. 02N-0278], 68 Fed. Reg. 5429-68 (February 3, 2003).

CHPA is generally supportive of the FDA's proposed regulation to implement Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (codified at 21 U.S.C. § 381)(hereinafter "Bioterrorism Act"). In the wake of the terrorist attacks of September 11, 2001, Congress has mandated with great specificity that importers of food shall notify FDA of the identity of each article of food being imported prior to its arrival in the United States. We recognize that the specificity of the law itself in many ways preordained the contents of these proposed regulations and leaves little flexibility to the agency. However, in several regards, CHPA encourages FDA to re-examine its position to make the implementation of the Bioterrorism Act less burdensome on industry while at the same time ensuring the safeguards that Congress sought to construct for the American public.

1. What is "Food"?

¹ CHPA, founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) medicines and nutritional supplements. Its membership comprises over 200 companies across the manufacturing, distribution, research, supply and advertising sectors of the self-care industry.

Section 307 of the Bioterrorism Act amends the Federal Food, Drug and Cosmetic Act (“FD&C Act”) to require that advance notice shall be given to FDA for “an article of food that is being imported or offered for import into the United States” for the purpose of “enabling such article to be inspected at ports of entry into the United States.” 21 U.S.C. §381(m)(1). FDA takes the position in the proposed regulation that “food” should be defined for purposes of this section in the same manner as “food” is defined in section 201(f) of the FD&C Act. 68 Fed. Reg. at 5430. This expansive definition includes as “food” such items as raw agricultural commodities for use as food or components of food, dietary supplements and dietary ingredients. *See* proposed 21 C.F.R. §1.277(c)(3). Industry does not question that both finished dietary supplement products and their components (both active and inactive ingredients) are squarely within the meaning of “food” intended by Congress.

A. Items that Have Food and Non-Food Uses

Moreover, CHPA agrees with the agency decision with respect to articles that can be used for food and non-food uses. FDA has clarified in the preamble that the prior notice requirement applies only if the article is being imported for use as food. 68 Fed. Reg. at 5430. If an article has non-food uses where human consumption is not a consideration, or particularly if it is intended to be used in another FDA regulated product which is subject to its own good manufacturing practices (e.g., corn starch imported for topical powders; corn sweeteners or flavorings intended as inactive ingredients in drug products), then it is clear that the prior notice import requirements for “food” do not apply.

What is not so clear is how this distinction will operate in the real world. CHPA members have raised concerns about the possibility that food ingredients intended for non-food (i.e., drug) uses may be held up as a result of confusion at the docks for what would be assumed to be a food. How might implementation of the Bioterrorism Act assure that items not intended to be regulated are not caught up in inadvertent “holds” on these products? Drug manufacturers sometimes import samples of “foods” for use in drug product formulation testing while these drug are still at the R&D stage. How can these “food” samples be differentiated from food intended for consumption in order to bypass the prior notice requirements?

Likewise, what about instances in which a food ingredient is imported and intended for use in drug product (thereby being exempt from the prior notice requirements) but, at a later date, the importer would like to use the ingredient in a food product (e.g., a dietary supplement which is produced in the same facility using the same food ingredient as a binder or flavoring as the drug for which the ingredient was originally imported)? Is there a process by which the notice can be remedied and the food ingredient used in the dietary supplement? How will an importer who sells component ingredients of drugs that are also food ingredients know what its buyers intend to use the ingredient in? If FDA has given

these matters some consideration, CHPA would appreciate some explanation how these issues might be resolved to prevent unnecessary “holds” on imported ingredients.

B. Food Packaging and Contact Materials

However, using the definition of “food” in section 201(f) of the FD&C Act would also encompass “substances that migrate into food from food packaging and other articles that contact food.” 21 U.S.C. §321(f). CHPA believes that Congress did *not* intend that all food packaging materials, as well as machinery and equipment that come into contact with dietary supplements or other foods during their manufacturing and processing, should be considered as “food” for purposes of the prior notice requirement. CHPA respectfully requests that FDA re-consider its position with respect to these materials.

Two separate references in the legislative history support this narrower interpretation. First, the Committee Report on the Act states that the requirement of prior notice should not be construed to apply to packaging materials if, at the time of import, such materials will not be used for or be in contact with, food. H.R. Rep. 107-481, 107th Cong., 2nd Sess., 137 (2002). Moreover, Representative Shimkus, one the sponsors of the Act, clarified that:

Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food.

148 Cong. Rec. E916, (May 22, 2002) (statement of Rep. John Shimkus).

Thus, it is clear from these statements, that prior notices should *not* be required where the packaging materials being imported might be intended to be used on food at a later date, but rather, only if, at the time of import, the materials are actually in contact with food. Of course, if the material is already in contact with the food, then subjecting the packaging on the food to notification imposes no additional burden on the regulated industry as such prior notice would already be required for the food itself irrespective of the packaging. Moreover, packaging materials that are not in contact with food at the time of import, but only *may* come into contact with food at a later date, pose a much smaller potential target for terrorism.

Elsewhere in the Bioterrorism Act, Congress refers to “food intended for consumption in the United States” as the criteria for requiring registration of food facilities. See 21 U.S.C. §350d(a)(a). In contrast, the prior notice provision makes clear that its requirements apply to all food passing through a United States port of entry (whether intended for consumption in this country for intended for export). But what is striking about the reference in §341 is that it is clear that Congress intended the law to apply to food *intended for consumption*, not for materials – like packaging or preparation surfaces – that are

clearly not intended for consumption, and thus, unlikely to pose a bioterrorism risk from the material itself. To that extent, a similar understanding of “food” (limited to only those things intended for consumption and not contact materials or packaging) should be applied here.

FDA’s ample authority in other areas of food regulation should not be overlaid onto the very specific requirements of the import prior provisions. Clearly, the broader definition of “food” found in the FD&C Act (that includes a definition of “food that does apply to packaging and contact surfaces) is necessary for FDA to exercise its authority to protect public health when it performs plant inspections that might unveil contaminated preparation surfaces, unsanitary conditions for packaging of foods, etc. In contrast, because this prior notice requirement applies inspection of only to the materials themselves and not the inspection of the processes and procedures by which foods are prepared and packaged, there is no need to provide FDA with prior notice before these items arrive at a port. Therefore, FDA should narrow the definition of “food” in its proposed regulations governing the prior notice of imports to exclude food packaging and other articles that will merely contact food, but are not themselves intended for consumption, unless they are already in contact with food at the time of entry.

2. Separate Notices for Separate Articles

CHPA’s second concern has to do with the FDA’s interpretation that that each article of food requires a separate and distinct prior notice. The agency reads the statutory requirement found in Section 307 of the Bioterrorism Act as requiring separate notice for each article. Thus, according to the agency, “any food product identified by a specific FDA product code and quantity description produced by a single manufacturer associated with a single entry line number” must be covered by a separate prior notice. 68 Fed. Reg. at 5435. FDA seems to recognize the great amount of duplication that will occur in cases where a single shipment includes a variety of products. The agency even offers that it is working with the developers of the prior notice system to accept ‘header’ information that will permit repeated information to be automatically entered. All of which begs the question: Does the statute really require that separate notices be filed for each “article of food”?

CHPA believes that the case for permitting a single notice of an entire shipment with separate line items for each “article of food” is more compelling. It would address the issues of reducing the amount of data entry and potentially reduce typing and transcription errors, as raised by the agency. *See* 68 Fed. Reg. at FR 5435. Likewise, it would reduce the workload for importers who would be able to combine a whole variety of products contained in a single shipment in a single submission. Congress has expressly instructed the Secretary to exercise discretion “to ensure that neither the requirements of the notice nor the timing of the prior notice be more burdensome than necessary to provide for the availability of food import inspection personnel.” Conference Report on H.R. 3448, Public

Health Security and Bioterrorism Preparedness and Response Act of 2002, 107th Cong., 2nd Sess., H2858 (2002). In the case of dietary supplement marketers who may be importing a variety of finished products for distribution or even a variety of raw ingredients in a single shipment, anything that reduces the burden of compliance would be welcome.

All notices will be required to be filed electronically so, presumably, FDA can manipulate the data it will receive in a single notice to extract only that information relating a single entry line number, or to retrieve all the information about a particular product line, or imports from originating particular regions, or whatever other criteria a situation might present. It is hard to imagine why separate electronic filings for each article in a shipment that contains many articles serve any purpose that offsets the amount of duplication and administrative burdens that this interpretation creates.

3. Timing, Frequency and Flexibility of Amended Notices

CHPA appreciates the thoroughness with which FDA approached the issue of establishing an appropriate timeframe for filing notices prior to importation. Initial filing of a prior notice is required no more than 5 days and not less than noon the day prior to the arrive of an import at a U.S. port of entry. *See* proposed 21 C.F.R. §1.286, 68 Fed. Reg. at 5461. It is curious though that once a prior notice is initially filed, the FDA proposes to limit the number of amendments to one. Proposed 21 C.F.R. § 1.290(b), 68 Fed. Reg. at 5462. Moreover, an importer may not change the identity of an article of food in an amendment or add additional articles to its notice. Proposed 21 C.F.R. § 1.290(c), 68 Fed. Reg. at 5462. The agency's concern for inefficient use of its review and planning resources addressing incomplete applications is understandable, but that concern should be balanced against the desire for complete and accurate information from importers that a more open amendment process would allow.

As proposed, the regulation discourages an importer from correcting information supplied in the initial prior notice if it becomes aware of the error, or from filing supplemental information (such as the exact quantity of a product) as soon as it becomes aware of it. The only permissible subjects of an amendment are those items relating to the identity of an article of food specified in proposed section 1.288(e). Other information such as the originating country (which may be different from the country from which the article is being shipped) and grower's identity are not subject to amendment. If an importer becomes aware of corrected information in these categories, its options are to: 1) cancel the initial prior notice and submit a new one (see proposed §1.289, 68 Fed. Reg. at 5462), which may cause a hold to be placed on the shipment and delay in receipt of the goods, or 2) do nothing, and hope that the error goes undetected.

Even with respect to information about the identity of the food, the agency's proposal would encourage an importer to wait until the very last minute to file an amendment in case additional information also becomes known (for example, if both the exact quantity of

food and the grower's identity are unknown at the time the initial notice is filed). In this dilemma, an importer would exhaust its one amendment by correcting or supplying the new information on the quantity of food. When the importer receives more information (in this case, the grower's identity), the importer must sit silently in violation (having exhausted its one amendment). So the incentive is created to hold any additional information that becomes known until the two-hour minimum permitted prior to the arrival of the import at the port of entry. That will surely tax the agency's resources if it can routinely expect to have revised information only two hours in advance of arrival. If the agency permitted multiple amendments (within reason) it might receive that first amendment shortly after noon the day before arrival rather than instilling the practice to hold all amended information until two hours ahead for fear that additional amendments might be necessary but would be impermissible.

This restrictive process also prohibits a foreign supplier from offering to fill out a cargo crate with additional products, apparently, a common practice in the industry. Late offers to add additional quantities or even additional products to a shipment at a discount make for more efficient commerce for importers and can provide economy and value to American consumers. Yet, because a notice can not be amended in this respect, the importer must say no or delay the receipt of its shipment by canceling the first notice and filing a new one.

4. A Conundrum for 'Grower's Identity'

CHPA also wishes to raise what appears to be a peculiar dilemma for importers who may not know the grower's identity of an article at the time of filing a prior notice (by noon the day before arrival). The proposed regulation would permit an importer to amend its prior notice to supply the grower's identity only if it is also amending the product identity. Proposed 21 C.F.R. § 1.290(d), 68 Fed. Reg. at 5462. However, for purposes of enforcing the regulation, FDA proposes to use an objective standard for grower's identity – if the information was objectively knowable, it must be reported, and failure to provide such information makes a prior notice inadequate. If you file a prior notice without the grower's identity (because you didn't know at noon the day before) but subsequently do receive that information, you are not permitted to amend unless there are other changes to the product identity that would trigger an amendment.² So an importer who subsequently receives a grower's identity after filing the initial prior notice is not permitted to file that information, and yet risks prosecution if it doesn't, as provided in proposed § 1.278(g).

² It is quite conceivable that when an importer of finished dietary supplements is filing a prior notice, it might not be aware of the originating country of the raw materials because it is importing from the country that manufactured the finished good and the foreign manufacturer receives raw dietary ingredients from multiple sources in other countries. If the importer can ascertain that information, even after it files the initial prior notice, wouldn't public policy be served by permitting the importer to amend that information?

Moreover, the FDA never receives that information as the importer sits quietly in hopes that the notice will be approved as initially submitted. Should there be a need to trace produce (e.g., raw botanical or herbal materials) from a particular grower later, FDA does not have that information available to it. It would seem to serve all parties better if an importer were permitted to amend a prior notice if any of the information in § 1.288 becomes available, or if the importer becomes aware of an error in the information provided up until the end of the two-hour window for amendments. As proposed, an importer is better off to “keep its silence,” hope the omission is not discovered, and then never provide the information to FDA at all.

5. Special Problems for Air Cargo

CHPA is concerned about the workability of the amendment process with respect to air cargo shipments. As a routine practice, air freight may arrive at a cargo hanger for shipment on a particular day, as agreed upon between the importer and the foreign seller, but the exact date and time of delivery to the United States are not confirmed. The arrival in the U.S will depend upon such factors as the total weight of all cargo ready for shipment to the United States, weather conditions in both the country of departure and the U.S. that may delay or cancel a flight, available space on a particular airplane in which to fit the shipment, etc. Given these uncertainties, it is hard to know the exact time of arrival in the United States within a four-hour window – particularly for relatively shorter flights from Canada, Mexico or even the United Kingdom (The proposed regulations require the shipment arrive no more than one hour before the predicted time nor three hours after the predicted time to avoid have to amend the notice with an updated arrival time. *See* proposed §1.294, 68 Fed. Reg. at 5462).

6. Amending Arrival Times

CHPA would appreciate clarification in the final rule that a change in the anticipated arrival information is not the same as a product identity amendment (§1.290) and therefore is not subject to the same mandates as that procedure for changes in the product identity. For instance, an arrival amendment should not be subject to the limitation that a prior notice can be amended only once (there could be repeated flight delays for the reasons described above, requiring more than one change to the anticipated arrival time). Nor should an arrival amendment be limited by the requirement that you must inform FDA of the intent to amend in the original prior notice (an importer would not know a day or two in advance that a cargo flight will be delayed). CHPA questions if there would be a separate, abbreviated form for filing these arrival changes, and believes a separate amendment form for this purpose would be helpful. Moreover, FDA should take efforts to make this change process as efficient and least burdensome as possible to industry to cause the least disruption of air cargo shipments that, by their nature, are extremely flexible.

7. Effects on Small Business

CHPA represents both large and small manufacturers and marketers of dietary supplements, and therefore, shares FDA's concerns about the potential effect of the implementation of these proposed regulations on smaller companies. CHPA notes that the agency has recently addressed a similar concern in the release of its proposed Good Manufacturing Practices (GMPs) regulation. (*see* 68 Fed. Reg. 12157-12263 (March 13, 2003)). In that case, the agency proposes a staggered implementation for dietary supplement manufacturers: one for larger dietary supplement manufacturers (defined as 500 or more employees, and another for small companies (defined as fewer than 500 employees). *Id* at 12247. If FDA believes that additional compliance time is needed for smaller business entities to acquire the necessary computer hardware and proficiency, CHPA suggests that, for sake of consistency, FDA use a similar threshold for defining small business in this context, but extend the compliance deadline only an additional 6 months. CHPA believes a modest extension for small business is not inconsistent with Congress' mandate that the Secretary exercise discretion "to ensure that neither the requirements of the notice nor the timing of the prior notice be more burdensome than necessary. . ."

As always, CHPA and its members are eager to work with the agency to implement the requirements of the Bioterrorism Act in a manner that assures public health but imposes the least burdens on industry that are needed to carry out the mandates of the law. We appreciate this opportunity to provide our views to the agency on this important topic.

Respectfully submitted,



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