

May 20, 2003

Via U.S. Priority Mail, Delivery Confirmation

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Re: Docket 03D-0092
Food and Cosmetic Security Guidances**

Dear Sir/Madam:

Nutraceutical Corporation submits the following comments on behalf of itself and its subsidiaries (together, "Nutraceutical") on the proposed draft guidance documents from the Food and Drug Administration ("FDA") entitled "Retail Food Stores and Food Service Establishments: Food Security Preventive Measures Guidance", "Cosmetics Processors and Transporters: Cosmetics Security Preventive Measures Guidance", "Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance" (collectively, the "Draft Security Guidance"). Nutraceutical is a manufacturer and distributor of dietary supplement and other nutritional products, as well as of cosmetic products, and also owns and operates retail health and natural food stores.

FDA has made a number of recommendations in the Draft Security Guidance that apply to retail food store and food service establishments, food establishment operations, food importing establishments and cosmetics establishment operations. The issues raised by the individual guidance documents overlap to such an extent that Nutraceutical has chosen to address the guidance documents collectively rather than each one individually.

Nutraceutical's comments on specific issues found in the Draft Security Guidance are set forth below. However, Nutraceutical also has three more general or overarching concerns. The first of these concerns is that the types of risks that the Draft Security Guidance try to address appear to be an inherent part of modern life that cannot be reduced or materially affected by even the most careful and thorough attempt to comply with the Draft Security Guidance. It simply is not possible to prevent an intentional and deliberate attempt to contaminate or poison many types of foods or cosmetics. This risk is present throughout the supply chain, and exists at stages that are not even addressed by the Draft Security Guidance, such as at the growing and harvesting stages. At various stages in the supply chain process, an individual with access to potentially lethal chemical or biological agents could overcome almost any

03D-0092

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conceivable security measures taken. Nutraceutical wishes to point this out because it is concerned that the FDA not mislead either itself or the public into believing that this type of risk is not present or that compliance with the Draft Security Guidance will materially alter these risks.

Nutraceutical's second overarching concern is that the Draft Security Guidance is not only unlikely to materially reduce the risk of contamination of the products it addresses, but is in fact more likely to create confusion and discrepancies in the way that various parties handle security issues. Because the Draft Security Guidance was issued in the form of "guidance" as opposed to regulations, compliance is optional. Furthermore, the nature of "guidance" is that it is far more vague than regulation. Because of these two factors, those food establishments that choose to attempt to comply are likely to interpret and implement the Draft Security Guidance in potentially significantly different ways, thus leading to discrepancies and inconsistencies that may in fact increase the risk of contamination. Furthermore, since various trade associations have already issued their own proposals to their members or are in the process of doing so, the likelihood of any consistent approach is further reduced or eliminated. The end result, unfortunately, is that the Draft Security Guidance may actually have the effect of creating increased risk. Nutraceutical therefore respectfully submits that it believes that the Draft Security Guidance is unnecessary and simply should be withdrawn.

Nutraceutical's third overarching concern is that attempts to enlist private industry and citizens in addressing the problem of terrorist and criminal activity in the United States is ultimately misplaced: it is the role of the State and Federal government to address these issues. Ultimately, the only way to materially reduce the risk of terrorist and criminal activity is for these agencies and Congress to do their job: passing tough laws against this type of activity and vigorously prosecuting offenders, monitoring and pursuing terrorist and criminal networks wherever they operate and putting an end to their activities, and improving and enforcing immigration laws and regulations so that we can either keep these types of individuals out of the country or expel them when they are found. To assume that private industry or the general public can somehow take the place of the state and federal agencies who are entrusted with public safety is simply a mistake.

To illustrate these general points, Nutraceutical has carefully reviewed the Draft Security Guidance and below sets forth more specific comments on individual provisions. As FDA will see, Nutraceutical's discussion of these provisions provides examples of why Nutraceutical has come to the conclusion that the Draft Security Guidance is unnecessary and should be withdrawn.

Management

FDA recommends providing an appropriate level of supervision to all staff, including *cleaning and maintenance staff*. This recommendation is difficult, if not impossible, to implement for many retail food stores and food service establishments. In many, if not most cases, cleaning

and maintenance staffs are employed by an independent third party that provides cleaning and maintenance services pursuant to a contract. These companies typically have keys to facilities and then hire janitorial personnel to provide cleaning and maintenance services on a regular basis, typically during non-working hours. Because janitorial staff must clean most if not all areas of a facility, they often have nearly unrestricted access to most if not all parts of the facility.

Placing the burden on the retail food store and food service establishment operators to “supervise” these non-employees seems to be an ineffective and overly costly method of addressing the potential that these individuals might choose to intentionally contaminate the food supply. A better approach might be to recommend that retail food store and food service establishment operators contractually require that their service providers undertake to meet certain minimum standards, including conducting background checks and providing adequate supervision and review of their personnel. The employers of these individuals are in a better position to evaluate, monitor and supervise their own personnel and the result would be more likely to prevent issues.

Notwithstanding, the question of security with respect to the janitorial industry has significant implications beyond the food service industry. Janitors typically have access to all or most areas of office buildings and manufacturing facilities at retail food stores, food service establishments, other food establishments and many other types of companies. Because of this broad access, a janitorial worker with criminal intentions would have the ability to intentionally cause harm or injury through various means, including planting concealed weapons or bombs, planting biohazards such as “anthrax,” or undertaking other potentially harmful steps. Given the potential breadth and magnitude of janitorial staff security issues, it may be appropriate and more effective for FDA in a rulemaking proceeding, or Congress through the legislative process, to consider and propose appropriate preventive measures that apply to all industries for which janitorial staff security is a concern .

FDA also recommends that retail food store and food service establishment operators conduct routine security checks of retail food store premises for “signs of tampering or malicious, criminal, or terrorist actions, or areas that may be vulnerable to such actions.” While the intent underlying this suggestion would appear to be laudable, the measure itself is unrealistic in light of the multitude of ways in which malicious or criminal or terrorist actions might be undertaken. Many fruits and vegetables are made available for display to customers, who often handle them prior to purchase. It would be fairly simple for a terrorist to contaminate or cause other malicious or criminal mischief in this area of any retail food store or food service establishment. Other examples abound, since many types of food are not protected by packaging, and even when they are, the type of packaging used is easily permeable and it is difficult to see evidence of tampering. Loaves of bread, for example, are contained within plastic bags that could be pierced by syringes without leaving any noticeable trace, or easily opened and then resealed without leaving any noticeable trace.

Human element - staff

FDA's recommendations under the title "Human element – staff" appear to underestimate the complexity and cost of conducting criminal background checks on staff, based on their access to "sensitive areas of the facility and the degree to which they will be supervised..." First, the term "sensitive areas of the facility" is never defined, and it is unclear whether this means anywhere that food is processed or handled (which theoretically might include the entire facility), or some other location. If the "sensitive areas of the facility" are in fact defined as the entire facility, then these types of background checks would need to be conducted on all employees. Second, the cost of actually conducting these types of checks would be prohibitive and certain state and local laws may potentially limit the information that may be obtained and may raise additional privacy issues. This recommendation also assumes that those individuals with actual criminal backgrounds are the persons most likely to contaminate the food supply; in fact, it may be the case that some other group of individuals is most likely to take these sorts of actions, such as those with financial ties to terrorist organizations who have no previous criminal record in the United States.

Restricted access

With regard to the recommendation that staff be restricted to certain areas of the facility, we note that this seems unrealistic in the retail food store and food service establishment industry. Retail food stores and food service establishments typically consist of an open retail section, fridges and freezers, and then storage or receiving areas, as well as a limited amount of office space. The only part of this space that could be restricted is the office space, which is not the area where the potential risk occurs. Additionally, this recommendation assumes that facilities involved in the manufacture of food have divisible areas and lockable doorways in between various areas. For those facilities which operate in an open area under a single roof, limiting access to staff to particular areas may be impracticable and/or impossible.

Human element - public

FDA recommends that incoming and outgoing vehicles, packages and briefcases be inspected "to the extent practical." This recommendation would appear overly broad and would be impractical for most food companies. The fact of the matter is that food manufacturing and processing facilities and retail food store and food service establishments cannot add inspection capabilities without security officers and installing significant upgrades in checkpoints and access points. These potential costs are simply prohibitive.

Additionally, the FDA's recommendations for retail food store and food service establishments operations for "monitoring public areas, including entrances to public restrooms... for unusual or suspicious activity" is overly broad and subjective. In effect, the FDA is recommending that retail food store and food service establishments record the time that a customer takes to select his/her produce, or employ a security guard and install expensive electronic monitoring

equipment to watch all areas of the produce section, from all angles (since the customer themselves could easily block the view of a single camera). This is simply impractical.

Facility

FDA makes various recommendations regarding facility security. Although it often qualifies these recommendations with the phrase “to the extent practical,” it bears noting that what is “practical” will vary significantly from one facility to the next, and the recommendation is therefore too vague to provide any useful guidance. Furthermore, even assuming that a particular facility can implement a recommended measure, there is no assurance that such measure will translate into heightened protection of the food supply. For example, FDA recommends that companies minimize “places that can be used to temporarily hide intentional contaminants (for example, minimizing nooks and crannies, false ceilings).” The fact of the matter is that if a person wishes to intentionally contaminate an item of food, that person likely will be able to do so, regardless of the availability of any particular nook or cranny. It is impossible to eliminate all such potential hiding spaces.

Operations

With regard to operations, FDA recommends that food establishment operators “reconcile the product and amount received with the product and amount ordered and the product and amount listed on the invoice and shipping documents, taking into account any sampling performed prior to receipt.” While this recommendation on its face may sound practical, it assumes that shippers and receivers operate in a realm of exactitude that simply does not exist. Food establishment operators place orders for a certain quantity and, as a matter of standard industry practice, often receive slightly less or slightly more than that quantity. Shortages typically occur for a variety of reasons – e.g., loss of some items in transit, failure of the shipper to completely fill the original order, or sampling by third parties, including the FDA. Tracking down the origin of these discrepancies is not practical, or, in many cases, even possible. It is simply unrealistic to assume that the exact quantities assumed by the Draft Security Guidance exist in this industry.

Additionally, with respect to retail food store and food service establishment operators, Nutraceutical’s prior comments that pertain to the amount of product ordered and the amount received also apply to retail food stores and food service establishments, particularly with regard to fresh produce. The amount of fresh produce ordered and the amount received are often different. There is no way to create exactitude in the process, since these items are even delivered in open boxes and crates. Items can be added or taken away or even altered. The only way a retail food store or food service establishment can affect this process is to review its transportation, loading, unloading and storage processes to try and restrict access. But access to these items can occur earlier, at the growing stage, at the picking stage, or at the produce markets where these items are offered for sale.

Food and Drug Administration
Docket No. 03D-0092
May 20, 2003
Page 6 of 6

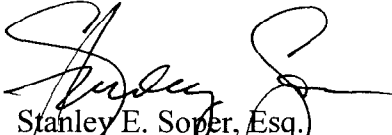
Also, it is very difficult to inspect or even notice signs of tampering, contamination or damage in goods that are not packaged or wrapped, which is much of what is sold at retail food stores and food service establishments.

Conclusion

Nutraceutical appreciates the opportunity to provide comments to the FDA regarding the Draft Security Guidelines. Nutraceutical agrees with the FDA's goal of protecting the food supply; however, Nutraceutical believes that the Draft Security Guidance does not support this goal and the cost of implementation far exceeds the potential benefits. Nutraceutical hopes that the FDA and other government agencies will carefully review this issue and determine the most effective means of reducing these risks. As stated above, Nutraceutical believes that the proper areas of focus are on stopping terrorists and criminals and the networks they operate through more vigorous enforcement of immigration laws, more aggressive enforcement of criminal laws, and increased monitoring and pursuit of criminal and terrorist activities in the United States and elsewhere. All of these steps are within the jurisdiction and power of state and Federal agencies and the Department of Defense, while none of them are within the power of food establishments and private citizens. Although all citizens and companies should be on the alert to help, in the end it is up to these agencies and our government – not specific industries or the general public – to address these issues.

Respectfully submitted,

Nutraceutical Corporation



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