NNFA

National Nutritional Foods Association

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Re: Docket No. 02N-0277; Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir/Madam:

The National Nutritional Foods Association ("NNFA") is submitting these comments to the Food and Drug Administration ("FDA") in response to the May 9, 2003 Proposed Rule "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ."

The National Nutritional Foods Association (NNFA) is the largest and oldest trade association representing the natural products industry. Our members include retailers, manufacturers and distributors of health food products, dietary supplements, and natural cosmetics.

NNFA recognizes that implementing Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") is in the public interest and will help the federal government respond quickly in the event of an attack on food safety. NNFA's primary concern in making these comments is to ensure that the proposed requirements actually forward the goal of safeguarding the public health. NNFA also aims to ensure that the burden imposed by the recordkeeping requirement does not outweigh the public health benefits to be gained.

I. Retail Facilities Should Be Exempt from the Recordkeeping Requirement

The proposed regulation would exempt retail facilities only from the requirement to establish and maintain records of the immediate subsequent recipient of food when the food is sold directly to consumers. Proposed 1.327(d)(1). The proposed rule would therefore require retail facilities to establish and maintain records of the immediate previous holder of all the food that it receives.

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NNFA takes the view that this partial exemption is misconceived. Instead, NNFA believes that retail facilities should be fully – rather than partially – exempt from the recordkeeping requirement. A full exemption would be consistent with the other regulations being promulgated under the Bioterrorism Act.

3931 MacArthur Blvd . Suite 101 - Newport Beach, CA 92660 - (949) 622-6272 - Fax (949) 622-6266 - www.nnfa.org

NNFA's perspective is based on the fact that there is no added public health protection from requiring retailers to establish and maintain records of the immediate previous holder of a food product. The proposed rule ensures that all information desired by FDA (e.g., the product and lot number going to a particular retail store) is already recorded by both the distributor of the product and by the transporter of the product. Proposed 1.345. Therefore, traceability of a product will exist without requiring the retailer to also keep that information.

In this context, it is worth noting that traceability of a food product by the distributor (and not the retailer) is a proven public safety tool. Currently, food recalls are implemented by manufacturers/distributors who have information about the retail facilities to which their products have been distributed. While such recalls are often based on product type and are thus over-inclusive, they are effective in safeguarding the public health. NNFA questions whether requiring retailers to also maintain records identifying the distributor-sources of each food product received will enhance the public safety already afforded by the proposed record-keeping regulations.

NNFA believes that the added burden of requiring retailers to establish and maintain records on immediate previous sources of the food it receives is not necessary based on the limited public health and safety benefit that would result.

II. **Small Businesses**

While NNFA fully supports the goal of safeguarding public health and safety in the event of bioterrorism, it is concerned about the net impact of the Bioterrorism Act regulations on small businesses. Taken together with the requirements that companies provide notification of imported food (68 Fed. Reg. 5426) and register with FDA (68 Fed. Reg. 5377), the proposed recordkeeping requirements may ultimately be unmanageable for many smaller companies.

The proposed recordkeeping requirements will require an ongoing attention to very detailed information about incoming and outgoing products – including the identification of the source of every ingredient in each lot produced by that facility (1.337(a)), and the recipient of each individual lot of each ingredient or product (Proposed 1.345). This may necessitate the addition of personnel and/or upgraded computer tracking abilities and may be too great a burden for small businesses.

By FDA's own estimates the costs incurred to a small or very small business complying with the proposed regulation would anywhere from $300 to $2500 dollars in startup costs, and then from $300 to $650 in recurring annual recordkeeping costs. 68 Fed. Reg. 25231-22.

In light of these estimated costs, NNFA suggests that FDA make clear that small businesses are exempt from the less necessary recordkeeping details required by the proposed regulation. For example, small businesses should not be responsible for identifying the source of each ingredient in different batches of products produced by them. In addition, small businesses should not need to track the destination of every lot number shipped. The goal, in this sense, should be to simply the regulations where appropriate so that the public health is safeguarded while small businesses are relieved of some part of the burden.

The goal of the Bioterrorism recordkeeping regulation is laudable. However, it should not have the unintended consequence of forcing small businesses out of the food industry.

III. **Requirement that Companies Keep Separate Records for Every Intra-Corporate Transfer is Burdensome and Duplicative** [Do we want to keep this argument? We do not think it is very strong]

The proposed rule would require companies to establish and maintain records for every specific location where a food is received or shipped out within a single corporate entity. In FDA's own estimation, this requirement would mean that corporations that transfer a product between facilities owned by the same corporation (e.g., from manufacturing to a packing facility to a retail store), would be required to establish and maintain records *in each location.*

NNFA believes that this requirement for intra-corporate recordkeeping is duplicative and does not add a public safety benefit commensurate with the added burden. The key to the proposed Bioterrorism recordkeeping requirement is that it allows FDA to track a tainted food/food ingredient back to the facility from which it came. To achieve this traceability, FDA needs to be able to identify the corporate entities involved in moving a food/food ingredient from source to destination.

Tracing a food/food ingredient within a single corporate entity does not, however, forward this traceability. Tracking a tainted food/food ingredient to a single corporation will sufficiently link the root of any contamination to that corporate source. Tracking it further within the corporation will not reveal how/where the contamination occurred.

Instead, intra-corporate recordkeeping will simply force the corporation to undertake unnecessarily duplicate record-creation and transfer between linked bodies. To ask a corporation to create multiples of paperwork simply because they have chosen to make a manufacturing and distribution process more efficient is burdensome and unjustified because there is little added public safety benefit.

In addition, there is a strong argument that keeping the recordkeeping requirement as simple as possible is the key to its effectiveness. Requiring an abundance of detail by too many entities in the food production and distribution chain could result in technical errors and a slowed response time, ultimately weakening the food safety chain. Requiring recordkeeping on intracorporate transfers is one example of too much detail where less will serve the same end. Thus, in the interest of simplicity, NNFA urges the agency to eliminate the intracorporate recordkeeping requirement from the final rule.

IV. **Conclusion**

NNFA believes firmly in the goals of food safety outlined by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and FDA's Proposed Rule. However, NNFA asks that FDA make clear that the requirement does not apply more broadly than necessary to ensure the safety of the U.S. food supply.

Sincerely,

David Seckman

David Seckman
CEO/Executive Director