GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES AND CONSUMER PRODUCTS

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July 8, 2003

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

Re: Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness Act of 2002; Notice of Proposed Rulemaking; Docket No. 02N-0275.

Comments of the Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to submit comments on the proposal of the Food and Drug Administration ("FDA") to implement the administrative detention of food provisions appearing at section 303 of the Public Health Security and Bioterrorism Preparedness Act of 2002 ("Bioterrorism Act").

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise of its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

1. *General Comments*

GMA and its member companies share FDA's goal of enhancing the security of the nation's food supply. Accordingly, our assessment of FDA's proposals to implement the Bioterrorism Act has been directly influenced by our deep and abiding commitment to provide a safe and secure food supply to the American people.

GMA appreciates the enormous task FDA has undertaken in developing a workable system for administrative detention of food. It is apparent that FDA has devoted considerable effort and thought to the administrative detention proposal. Nevertheless, GMA is greatly concerned by several provisions of the proposal, and we believe that revisions are essential, if the administrative detention procedures are to function as Congress intended.

The Bioterrorism Act gives FDA substantial authority with respect to administrative detention of food. The agency orders and approves the detention, presides over any informal hearing, renders judgment confirming or terminating the order, and initiates seizure and injunction actions, thereby extinguishing claimants' rights to appeal the detention order. And, according to FDA, it even has discretion with regard to whether to grant a hearing request.

To protect the interests of owners of food that may be subject to administrative detention, Congress provided a number of procedural safeguards that serve as checks on FDA's detention powers. These include: (1) a limit on the duration of the detention period; (2) approval of a detention order by an officer senior to the official ordering the detention; (3) entitlement to appeal the detention order; (4) an opportunity for an informal hearing; (5) termination of the detention order, if within five days of the filing of an appeal, the agency fails to provide an opportunity for an informal hearing, and confirm or terminate the detention order; and (6) a requirement that procedures be promulgated to expedite detentions with respect to perishable food.

We believe that the above procedural safeguards serve not only industry, but FDA as well – since it shares a substantial interest in ensuring that erroneous detentions are avoided, or identified as early as possible, to minimize resulting losses and reductions in the marketability of detained foods. We do not believe, however, that the proposal adequately ensures the effectiveness of these procedural protections. Consequently, GMA believes that significant revisions are needed in order to protect against the imposition of unnecessary and

potentially enormous costs for the food industry, and ultimately the nation's consumers.

2. *Specific Comments*

a. *FDA's Proposed Perishable Food Definition Excludes Many Foods Likely to Suffer Loss or Reduction in Marketability If Erroneously Detained*

Having recognized the special vulnerability of perishable foods to loss or reduction in marketability, Congress directed FDA to promulgate by regulation procedures for their detention on an expedited basis. The Bioterrorism Act does not define perishable food. The definition provided at section 1.377 of the proposal would encompass only certain foods that are "not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions." FDA has specifically invited comments regarding this definition. GMA believes this definition to be too narrow.

Many foods with a shelf life of greater than seven days may suffer loss or significant reduction in marketability, if detained subject to the procedures applicable to non-perishable food. Not surprisingly, a large percentage of food products bearing expiration dates are subject to shorter and more frequent shipment cycles. Very often, when delivery of such products is delayed, more recently packaged and shipped product – bearing more distant expiration dates – will already have arrived to market. Notably, however, when consumers shop for such products, they typically favor those bearing more distant expiration dates. In recognition of this preference, retailers and distributors are more likely to reject delivery of a shipment of potato chips, for example, if it bears a less distant expiration than comparable products that may also be available. Thus, even relatively brief administrative detention can render these products unmarketable, even though they may remain fresh at the time of release from detention. Moreover, given the shorter shipment cycles for these foods, delayed delivery often will lead to periods in which the product is simply unavailable. In order to better ensure that administrative detentions of food do not unnecessarily render such products unmarketable, the definition of perishable food should be revised to include food with a shelf life of 90 days or less.

b. *FDA's Proposal Would Do Nothing to Expedite Release of Erroneously Detained Perishable Food*

As noted above, Congress recognized that administrative detention subjects perishable food to added risks with respect to loss or reduction in marketability, and accordingly, directed FDA to promulgate procedures by which to expedite their detention. Congress doubtlessly intended that the regulation it mandated would achieve accelerated termination of detention orders and release of the detained perishable food, in cases where the agency finds there to be a lack of credible evidence or information that the detained article poses a threat of serious adverse health consequences or death. The regulation FDA has promulgated to implement this directive, however, would do nothing to expedite release of such food.

Peculiarly, FDA's proposal imposes on the agency no enhanced responsibility for directly effectuating the expeditious release of erroneously detained perishable food. For example, under both section 303(a) of the Bioterrorism Act and FDA's proposal to implement it, an appeal of a detention , whether for perishable or non-perishable food, may be filed two days after receipt of a detention order, and in such cases, FDA must confirm or terminate the order within five days. Surely, however, Congress would not have mandated that FDA promulgate a regulation to expedite procedures with respect to perishable food, if it intended the regulation to do nothing to accelerate FDA's rendering of confirmation or termination of the order. Moreover, given the proposed limited definition of perishable food, even a successful appeal filed two days after receipt of an order detaining a perishable food will, under the proposal, win the release of the product after its marketability has been lost, five days later. One should not be surprised, therefore, if prospective claimants are discouraged from exercising their right to appeal detentions of perishable food.

Instead of expediting the confirmation or termination of detention orders – the outcome with which Congress and affected parties are ultimately concerned – FDA's proposal seeks to expedite the convening of any informal hearings that the agency may grant with respect to the detention of perishable food. In furtherance of this objective, FDA would require that it conduct any hearing it deigns to grant in relation to perishable food within two days of the filing of an appeal, in contrast to the three days allowed in the case of non-perishable food. Since the timing of the hearing has no direct impact on the rendering of the agency's confirmation or termination of the detention order, FDA's proposal

would have no inherent effect on expediting the release of erroneously detained perishable food.

Notably, Congress' directive that FDA promulgate procedures to expedite detention of perishable food appears at subsection 304(h)(2) of the Federal Food, Drug and Cosmetic Act ("FDC Act") (as added by section 303(a) of the Bioterrorism Act), a provision relating to the "period of detention." FDA's proposal to implement this directive, however, relates only to appeals of detention orders, a subject addressed at subsection 304(h)(4). Congress' decision to place its mandate for the expediting of administrative detention procedures for perishable foods in the subsection entitled "period of detention," rather than in the subsection entitled "appeal of detention order," indicates its intent that FDA take direct action to accelerate the pace with which erroneously detained perishable food may be released, not merely the pace at which an informal hearing may be convened.

FDA proposes to place much of the burden of expediting such hearings on the claimants themselves. Whereas the Bioterrorism Act imposes no specific deadline on the filing of an appeal with respect to perishable food detentions, the proposal would require that such appeals be filed within two days of the receipt of the detention order. Prospective claimants who fail to appeal within two days would lose their right to appeal the detention. In contrast, appeal of a detention of non-perishable food need be filed within four days, if requesting an informal hearing, or ten days, if no hearing is requested. Congress required promulgation of the expedited procedures in order to safeguard rights with respect to perishable food, and FDA's proposal to restrict the rights of prospective claimants to appeal detention of such food is inconsistent with that objective.

FDA expedites its rendering of the confirmation or termination of detention orders only in response to appeals, and then, ironically, only with respect to non-perishable foods. To illustrate, if appeal and request for informal hearing are filed two days after receipt of a detention order for both a perishable and non-perishable food, FDA would require that it hold any hearing by the fourth day for the former and by the fifth day for the latter. In both cases, however, section 304(h)(4) of the FDC Act (as amended by section 303 of the Bioterrorism Act) requires that FDA render its decision on appeal by the seventh day. Thus, FDA would allow itself three days after an informal hearing to render its decision with

respect to the perishable food, but only two days with respect to the non-perishable food.

Notably, the deliberative process presents no greater challenge with respect to perishable food. To afford itself a longer period of deliberation in the case of perishable food is inconsistent with Congress' clear intent. FDA has implicitly acknowledged its capacity to render judgment within two days of an informal hearing with respect to non-perishable food. To ensure that FDA act in at least as expeditious a manner as it provides for non-perishable foods, GMA recommends that FDA expedite its decision making following an informal hearing to require judgment on appeal within two days after a hearing is held for both perishable and non-perishable food.

c. *The Proposal Would Violate the Bioterrorism Act By Permitting Extension of a Detention Order for Longer Than Is Reasonable*

Pursuant to section 303(a) of the Bioterrorism Act, section 304(h)(2) of the FDC Act provides for the detention of an article of food "for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable [FDA to initiate a seizure or injunctive action]." (Emphasis added). The principal determinant of the duration of the detention is reasonableness. Thus, food may be detained no longer than reasonable, and for no more than 20 days, unless additional time is needed to initiate a seizure or injunctive action, in which case, the detention may be extended only so long as is reasonable, and for no more than 10 additional days.

Notably, the element of reasonableness appears to have been excised from FDA's proposal. Section 1.379(a) of the proposal provides that "an article may be detained for 10 calendar days if a greater period of time is required to institute a seizure or injunction action. The authorized FDA representative may approve the additional 10 calendar day period . . . ." (Emphasis added).

By referring to the optional extension as if it were a fixed 10-day period, FDA suggests that it will seek the maximum amount of time available, whenever more than 20 days of detention are needed. In its final rule, FDA should clarify that it will, in all cases, order the detention of articles of food for only so much time as is reasonable, and that the 10 calendar day period constitutes the maximum number within the range of additional days that it may order.

d. *FDA Proposes to Withhold Information Necessary to Effective Appeal of Detention Orders*

Section 304(h)(4) of the FDC Act (as added by section 303(a) of the Bioterrorism Act) provides the right to appeal detention orders, as well as the opportunity for an informal hearing to challenge such orders. As FDA noted in the preamble to its proposal, a purpose of the detention order is to serve notice of the right to an informal hearing to appeal the detention. Unless claimants are adequately informed as to the basis upon which detention has been ordered, however, such appellate rights are simply not meaningful.

Section 1.393(b)(6) of the proposal provides that a detention order must specify "[a] brief, general statement of the reasons for the detention." Peculiarly, although the statement must include less important information, such as whether the order was approved in writing or orally, it need not inform prospective claimants of the credible evidence or information that led FDA to conclude that the article of food poses a threat of serious adverse health consequences or death.

Prospective claimants have very little time with which to file an appeal of a detention order. In fact, in the case of perishable food, FDA proposes to require that appeals be filed within two days of receipt of the order. Since, in most cases, such limited response time will effectively prevent comprehensive investigation by the prospective claimant, withholding the evidence supporting the detention may prevent both the preparation of an effective appeal and the assessment of the likelihood of prevailing on appeal.

GMA recommends that section 1.393 be revised to require that detention orders provide notice of the credible evidence or information supporting FDA's conclusion that the detained food poses a threat of serious adverse health consequences or death. Importantly, provision of such information would require no further investigation by the agency, since issuance of the order signifies that the information is already in its possession. Disclosure would be subject to exceptions relating to classified information, as provided by section 1.406 of the proposal. Requiring the agency to more fully disclose the basis upon which the order was issued, would facilitate avoidance of impermissible detentions, as well as greater and more rapid identification of improper detentions, thereby minimizing the costs to affected parties.

e. *FDA Proposes to Withhold the Opportunity for the Informal Hearing that Congress Required*

Pursuant to section 303(a) of the Bioterrorism Act, section 304(h)(4) of the FDC Act directs FDA to provide appellants with "the opportunity for an informal hearing" within five days of the filing of an appeal. FDA interprets this directive as merely requiring notice of the opportunity to request such a hearing, with the granting of such requests left entirely to the agency's discretion. As the agency explains, "[u]nder this interpretation, a failure to provide an opportunity for a hearing means a failure to provide you with notice of your opportunity to request a hearing." The agency's interpretation is inconsistent with the plain meaning of the text, the context in which it appears, the legislative history of the provision, and due process guarantees afforded under the Fifth Amendment to the Constitution. Accordingly, FDA should revise its proposal to ensure that claimants receive an actual opportunity for an informal hearing, as Congress intended.

First, FDA's interpretation equating the opportunity for an informal hearing with mere notice of the opportunity to request a hearing flies in the face of the plain meaning of the statute. Had Congress intended to require mere notice of the opportunity to request a hearing, it could readily have said as much.

Second, the context in which the directive to provide an opportunity for an informal hearing appears further demonstrates the erroneousness of FDA's interpretation. If Congress intended only to require notice of the opportunity to request such a hearing, it would have required that such notice be given at the time the detention order is issued, since doing so would impose virtually no additional costs on the agency. Instead, the statute directs FDA to provide the opportunity for an informal hearing within five days after an appeal is filed. In fact, by threatening termination of a detention order where FDA fails to provide opportunity for a hearing within five days of the filing of an appeal, Congress signaled the degree to which it deems such hearings important. It is simply unreasonable to conclude that Congress would have endowed mere notice with such gravity, while at the same time needlessly withholding delivery of that notice until after a claimant files an appeal.

Third, the legislative history of the provision reveals that Congress did not intend to give FDA discretion to grant or deny requests for hearings. In fact, the Conference Committee report accompanying the Bioterrorism Act states: "The

Conference substitute requires the Secretary in response to an appeal filed by a claimant challenging the detention of an article of food to conduct an informal hearing and confirm or terminate a detention order within five days after an appeal is filed . . . ." H.R. Conf. Rep. No. 107-481, at 131 (2002) (emphasis added). Here, the use of the word "conduct" demonstrates Congress' intent that the agency engage in the act of administering an informal hearing.

Fourth, administrative detention of food constitutes a deprivation of property and, consequently, such actions are subject to the due process clause of the Fifth Amendment to the Constitution. FDA estimates that the potential cost to small entities of each administrative detention would be $20,000 to $330,000, but acknowledges that "the actual range of potential costs for a single detention would be much larger." To make matters worse, the proposal makes no provision for compensating affected parties for the costs they may suffer due to erroneous detentions. Accordingly, the degree of deprivation to which FDA may subject owners of food property may be enormous.

Moreover, the agency states that it cannot confidently estimate the percentage of times that it will erroneously order the administrative detention of food. It does acknowledge, however, that during the first nine months of 2002, it released 48 percent of the import shipments of food that it detained. FDA points out that this represents the upper limit of that which it can expect to erroneously detain pursuant to its administrative detention proposal. Even a fraction of this percentage would constitute a substantial, unnecessary burden to the producers, importers, wholesalers, retailers, transporters, and food service establishments that FDA states may be affected by its proposed rule. When one considers that nearly half of administrative detentions may be erroneous, that the potential costs of detention may be enormous and are likely to be borne by small businesses, and that the proposal makes no provision for compensation for erroneous detentions, the critical importance of FDA's procedural protections becomes especially evident.

Unless owners of food subject to administrative detention are guaranteed the opportunity for an informal hearing, as Congress mandated, in many cases, they will possess no meaningful opportunity to challenge the deprivation of their property. In fact, under the proposal, prospective claimants possess no opportunity for a pre-deprivation hearing. Since they cannot reasonably anticipate the basis upon which their food may be subjected to administrative detention in the future, they lack the capacity to request consideration of such

factors during the notice and comment process. And, they have no reasonable access to judicial appeal in time to avoid complete loss of marketability of their detained food. To additionally deprive such parties of the opportunity for an informal post-deprivation hearing would constitute a violation of prospective claimants' rights to due process.

FDA's interpretation of Congress' directive that an opportunity for an informal hearing be provided conflicts with the plain meaning of the statutory language, the context in which the directive appears, the legislative history of the provision, and constitutional guarantees provided pursuant to the due process clause. Consequently, FDA should revise its proposal to guarantee the actual opportunity for an informal hearing.

f. *FDA Fails to Ensure That the Officer Presiding Over an Informal Hearing Is Senior to the Official Who Approved the Detention*

Section 1.404 of the proposal provides that the officer presiding over an informal hearing on appeal of a detention order must be senior to an FDA District Director. FDA explains this provision by noting that it is important that the presiding officer be senior to the person who approved the detention order. This sound principle is consistent with Congress' mandate that the official approving a detention order be senior to the person issuing the order.

FDA appears not to have recognized, however, that detention orders may be approved, not only by a District Director, but also by an FDA official senior to such director. Thus, the proposal appears to inadvertently authorize officials at the same level of seniority to both approve a detention order and preside over an informal hearing on appeal of the detention order. The agency should revise its proposal to specify that the presiding officer shall be senior to the official who approved the order being appealed.

3. *Ways to Create a Workable Administrative Detention System*

GMA has compiled numerous suggestions to create a workable administrative detention system. In compiling these suggestions, we have been guided by several principles, each of which GMA shares with FDA: (1) unnecessary burdens and deprivations of property should be reduced or eliminated; (2) adequate procedural safeguards must be ensured; and (3) fidelity to the word and spirit of the statutory language establishing the administrative detention system must be maintained. These suggestions are summarized below.

- **Revise the Proposed Definition of Perishable Food to Include Food with a Shelf Life of 90 Days or Less**

The definition of perishable food should be extended to cover foods with a shelf life of 90 days or less. While the Bioterrorism Act does not define perishable food, it does evince Congress' intent that all reasonable efforts be made to avoid the unnecessary loss or reduction in marketability that may result from erroneous administrative detention. Many foods with shelf lives substantially greater than seven days are at risk of losing or suffering a reduction in marketability, if detained for more than seven days. By extending the definition of perishable food to those with shelf lives of up to 90 days, such harms can be minimized.

- **Confirmation or Termination of Orders Detaining Perishable Food Should Be Rendered Within Two Days of an Informal Hearing**

FDA proposes to render a confirmation or termination of an order detaining a non-perishable food within two days after holding an informal hearing. FDA should require that its decisions with respect to perishable food be rendered at least as quickly. Failure to do so directly conflicts with Congress' directive that FDA establish expedited procedures for administrative detention of perishable foods.

- **Detention Orders Must Not Be Extended for Longer Than Is Reasonable**

FDA should clarify that, when more than 20 days of detention are needed to initiate a seizure or injunction action, it will approve an extension of only so much time as is reasonable, up to a maximum of 10 additional days. This clarification is needed because the proposal refers to the option of additional days of detention as if it encompassed a fixed 10-day period. In contrast, section 304(h)(2) of the FDC Act provides that the extension must be for a "reasonable period."

- **Detention Orders Should Disclose the Credible Evidence or Information Upon Which Approval of the Order Is Based**

Prospective claimants will be hindered in their ability to effectively appeal detention orders, unless such orders provide notice of the credible evidence or information supporting FDA's conclusion that the detained food poses a threat

of serious adverse health consequences or death. Disclosure of this information can be made subject to the limitations applicable to classified information. Since FDA is prohibited from approving administrative detentions in the absence of such information, providing such notice at the time that the order is approved would require no additional investigation by the agency.

- **FDA Must Provide an Actual Opportunity for an Informal Hearing**

The Bioterrorism Act requires that prospective claimants be provided an opportunity for an informal hearing. FDA has misinterpreted this directive as requiring only that notice of the opportunity to request a hearing be provided. The agency's reading of the provision is inconsistent with the plain meaning of the statutory language, the context in which it appears, the legislative history of the provision, and the due process protections guaranteed by the Constitution.

- **The Officer Presiding Over an Informal Hearing Should Be Senior to the Official Who Approved the Detention Order**

FDA has indicated the importance of ensuring that the presiding officer of an informal hearing be senior to the official who approved the detention order being appealed. However, by requiring only that the presiding officer be senior to an FDA District Director, the proposal fails to ensure the relative seniority of the presiding officer, where the detention order was approved by an official who is also senior to an FDA District Director. In order to promote accountability and reduce the potential for biased decision making, FDA should clarify that that the presiding officer must be senior to the official who approved the detention order.

4. *Conclusions*

GMA appreciates the difficulty that confronts FDA in balancing the security of the nation's food supply against the importance of preserving the ability of the nation's food industry to provide consumers with healthful food products in an efficient manner and at an affordable cost. We are concerned, as these comments reflect, that the administrative detention system that FDA has proposed fails to provide the procedural safeguards that Congress mandated. Thus, we believe the proposal fails to ensure that food will not be unnecessarily and erroneously detained. Moreover, the system FDA has proposed simply will

not serve to adequately identify and secure the timely release of erroneously detained articles of food.

These comments identify numerous serious problems with the proposal and provide suggested approaches to remedying them. We strongly suggest that FDA reexamine its proposal with the goal of minimizing unnecessary detentions and promoting more effective methods for early identification and release of erroneously detained food.

GMA member companies have an abiding interest in the security of our nation's food supply. Revision of FDA's administrative detention proposal, however, is necessary to preserve the ability of America's food industry to meet the public's demand for healthful and affordable food products, and to deliver them efficiently.

Sincerely yours,

Susan M. Stout

Susan M. Stout
Vice President, Federal Affairs