



American Pet Products Manufacturers Association, Inc.®

April 4, 2003

Stuart Shapiro
FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Building
Room 10235
725 17th St. NW
Washington, DC 20503

Submitted to:

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

Re: Docket No. 02N-0276 --Notice of Proposed Rulemaking - Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 Fed. Reg. 5377, February 3, 2003)

Dear Mr. Shapiro:

The American Pet Products Manufacturers Association, Inc. (APPMA) is a trade association representing approximately 650 pet product manufacturers. Close to 40% of our members are small manufacturers, i.e., with gross annual sales of less than \$500,000 nationally. We represent many larger manufacturers as well. Our industry employs more than 250,000 individuals in the manufacturing, distribution and marketing of pet products, many of which include manufacturers who make pet food, treats, supplements, as well as, other pet care products necessary for the health and welfare of companion animals. A national

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survey of pet owners conducted by APPMA shows that there are as many as 280 million pets in the United States and that 62% of American households have at least one pet. **Be they furry, feathered or finned, Americans love their pets.**

Moreover, this year, APPMA hosted the largest annual pet products trade show in the world, distinguished in the Trade Show 200, a listing of the largest shows in America. In fact, 8,000 visitors came to see products from all over the world on a show floor totaling 300,000 gross square feet. Our exhibitors provide animal food products to American consumers that can be made overseas or include ingredients or components from overseas. The APPMA Show is a three-day event in which it is critical that exhibitors are able to ship product into the US in a timely fashion, show products in booths and otherwise pursue trade freely as permitted by law.

APPMA appreciates the opportunity to submit these comments regarding the above-referenced proposed rule for the registration of food facilities. The US Food and Drug Administration (FDA) was given a challenging and worthy task in implementing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 21 U.S.C. 331 et seq. (2002), especially given such a short timeframe for publication of final rules. We fully support the need to safeguard the US food supply from terrorist threats and acts and hope to contribute to the maintenance of controls already in place to assure this. However, we believe that sections of the proposed rule are overly burdensome without providing added protections that the Act intends.

The Act requires the registration of all facilities that manufacture, process, pack or hold food for human or animal consumption in the United States by December 12, 2003. Detailed information regarding the company, facility location and product type(s) are required. Incomplete registrations will not be accepted and cancellations must be reported on separate forms. Failure to comply can result in civil and criminal action, as well as, food held at the port of entry or at a secure location, as prescribed by FDA.

The required information is too detailed to allow for easy compliance and does not fulfill the intent of the Act. While basic product and company contact information can be useful for FDA, additional information such as type of activity conducted at the facility; additional food product categories at the facility; type of storage and dates of operation for seasonal facilities are all facts that can change regularly. This would require companies to constantly check their submissions and update accordingly. In addition, electronic and written submissions may be too limited. FDA should consider alternatives such as by phone and fax in order to provide the maximum possible mechanisms to comply.

We also believe that more flexible alternatives utilizing pre-existing controls would better serve the purpose of the Act, as well as, assist the Agency in its effective implementation of the Act. FDA proposes to take on the colossal task of tracking all facilities that provide food for consumption in the United States (by its own estimates over 400,000) by imposing a system on industry that ignores other reporting requirements and data that has been collected by, not only other federal agencies, but by FDA itself. Industry is expected to start from scratch by providing information in a form that is overly detailed on an unfamiliar system that has not been tested.

Moreover, relying on only two means of reporting could jeopardize the security of the entire system if the electronic system is down. In fact, given the fact that FDA expects its electronic system to be in place in October and all facilities to be registered by the December deadline while refusing to accept earlier registrations, there is a likelihood that the FDA electronic registration system will be overloaded by the immense volume of activity from the rush to register.

Lastly, we request that FDA provide a grace period to allow the many potential registrants to become aware of the new requirements and comply. This is particularly important for our members who exhibit at the APPMA annual trade show. Many times exhibitors ship products to the trade show for the limited purpose of exhibition and ship goods back to their respective facilities with their display equipment. An exhibitor who is ignorant of the new registration, as well as, the prior notice of imported food articles requirements could find itself in the unfortunate position of having an empty booth because the goods are being held at the port of entry or a secure location. We hope to avoid these incidents, as much as, possible by educating our members and otherwise assisting them with the rising challenges of manufacturing pet products. However, a grace period would ensure that trade is not hindered.

We respectfully submit our views.

Sincerely yours,



Gina Valeri
Director of Legislative Affairs & General Counsel