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Date: March 28, 2003

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

To Whom It May Concern:

We are submitting comments in regards to the Bioterrorism Act (Public Health Security and Bioterrorism Preparedness and Response Act of 2002), which includes a number of provisions that will affect the import industry. Although we understand the importance of ensuring the safety of our food supply, we are very concerned about the implementation and enforcement of these regulations. We have listed the Section followed by our concerns and comments.

> Sec 303. Administrative Detention
> Allows an officer or qualified employee of the Food and Drug Administration to order the detention, in accordance with the subsection, of any article of food that is found during an inspection, examination, or investigation under this Act conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information that such article presents a threat of serious adverse health consequences or death to human or animals.

Concern: What is considered a qualified employee of the USFDA? Does this include a clerk who does data entry or a secretary that answers telephone calls? This section should be amended to specifically state that only a compliance officer or inspector of the Food and Drug Administration may order the detention...

> Sec 303. Administrative Detention
> Also allows an article of food to be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) or section 302.

Concern: The specifying of 20 days, as an upper limit, is not what most would consider a reasonable time frame to institute an action. In addition, from when does the period of detention begin? The period of detention should begin once prior notice (as stated in Sec 307) is filed for the article of food. In addition, the article of food should only be detained for 72 hours so that the Secretary is enabled to institute and action.

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Sec 305. Registration of Food Facilities
Mandates that all facilities that engage in the manufacturing, processing, packing, or holding of food for the consumption in the United States be registered with the Secretary. To be registered--
"(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and
"(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

Concern: This section clearly states that for a foreign facility, a United States agent must be designated. The United States agent so designated must be a permanent resident or citizen of the United States. Both foreign exporters and US importers are therefore at substantial risk if the designated United States agent for the foreign facility fails to fulfill its obligations to that foreign facility. Both will lose control if they are compelled to have communications with FDA channeled through a United States agent. A foreign facility must be able to submit a registration to the Secretary without designating a United States agent.

Sec 305. Registration of Food Facilities
States that the Secretary shall compile and maintain an up-to-date list of facilities that are registered under this section. Such list and any registration documents submitted pursuant to this subsection shall not be subject to disclosure under section 552 of title 5, United States Code. Information derived from such list or registration documents shall not be subject to disclosure under section 552 of title 5, United States Code, to the extent that it discloses the identity or location of a specific registered person.

Concern: This section does not make sense since it prohibits a domestic or foreign facility from verifying whether proper registration has been completed for each facility that manufactures, processes, packs, or holds food for consumption in the United States. Therefore, the facility cannot acquire verification that all foreign entities in the supply chain previous to the facility have properly registered before the facility possesses the article of food.

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> Sec 307. Prior Notice of Imported Food Shipments
> States requires that a notice under such paragraph be provided by a specified period of time in advance of the time of the importation of the article of food involved or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days.

Concern: Since prior notification must be given and the notification requires certain information, including Customs entry number, the importer must pre-file their entry with US Customs. However, US Customs also has a regulation that does not allow an importer to file entry more than five days before arrival. This effectively reduces the window accorded an importer to submit prior notice of imported food. With the port situation, it is becoming harder to pinpoint arrival information for shipments. Sometimes the freight company does not provide arrival information on shipments until it has arrived at the border. The regulation governing Prior Notice of Imported Food Shipments is also a redundancy of the current OASIS system that is already in place and working. The custom broker of the importer of record already provides a list of information to the US FDA. To have the importer provide the same information in the Prior Notice of Imported Food Shipments would be a redundancy. In addition several fields of information is not known to the importer, such as the US FDA product code of each item. Therefore, the Prior Notice of Imported Foods shipments serves no need and should not be implemented.

> Sec 307. Prior Notice of Imported Food Shipments
> In the event that other information in the prior notice must be changed, no amendment or update is permitted. The submitter must cancel the initial prior notice and submit a new one. In addition, if an amendment is needed, FDA is proposing to limit the information that may be amended in a prior notice to the product identification information required in proposed Sec. 1.288(e)(1).

Concern: Under the proposed US FDA regulation, a prior notification filing cannot be amended if an error was made in the filing. The filing must be discarded and a new prior notification is submitted. This will be an enormous drain of resources for both the importer and the US FDA because each filing will take 0.5 to 1 hour to complete for each article of food. In addition, if the clerical error is not discovered before noon of the day prior to arrival, the shipment will be refused.

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Sec 307. Prior Notice of Imported Food Shipments
FDA recognizes that food may be shipped in the same container or truck with non-food items. Since articles that are not food are not subject to this proposed rule, when mixed or consolidated imported freight contains articles of food that must be held at the port of entry or moved to a secure facility, those articles that have been refused must be dealt with before the rest of the shipment proceeds.

Concern: This proposed regulation appears to place undue burden on importers who often use mix or consolidated imported freight to import their goods. If one importer does not properly file a prior notice of imported food shipments, then the other importers must wait for the offending importer to deal with the prior notice of imported food shipments before the consolidated or mixed imported freight shipment can proceed. Importers can face substantial delays awaiting clearance of products.

We, as members of the international trade community, are very concerned about the current situation with importation as well as the future implementation of the Bioterrorism Act and subsequent regulations. As it stands, the international trade has been severely hindered and slowed by the increase in the number of inspections and regulations. With the likelihood that there will be an increase in regulations, procedures, and filings under the implementation of the Bioterrorism Act, the length of time to receive imported merchandise as well as the cost of importation will only increase. By adding another federal agency that will institute its own sets of Bioterrorism regulations, this will only cause redundancy that is not needed since US Customs and the USDA have already increased inspections at our border in regards to Bioterrorism. We see this as extraneous security that will not aid in the fight against Bioterrorism and a waste of human and financial resources.

Sincerely,

Oriental Herbal Association Member