FDA IMPORT DETENTION TESTING

If you would like PrimusLabs to perform compliance testing for products on automatic FDA Import Detention, please follow the steps below and provide the required information. Your Customs Broker is your best source for all of this information.

All lots to be sampled shall be separated and marked by Entry # and Line Item as shown on the Notice of FDA Action form. If more than one (1) lot is to be sampled then each Entry # and Line Item must be physically separated from the others.

If there are multiple Line Items on one Entry # for the same product that are detained, the FDA protocol requires that all Line Items be sampled and analyzed separately. It does not matter if the differences are only product size, package size, color, etc. if the Line Items are detained they must be done individually.

Any deviation from the FDA protocol must be approved in writing by the FDA prior to sampling.

All sampling must be done by PrimusLabs personnel as we are required to utilize specific FDA sampling protocols based upon the commodity to be tested and the size of the lot that has been held. Sampling cannot be done until the product has crossed into the United States and has been entered into the FDA's system.

The sampler must not be told what to sample or from where to sample; they are to be shown where the specified Entry # has been placed. The sampler will get direction from the laboratory with regard to sampling requirements. The only assistance allowed is with gaining physical access to the material (moving boxes, opening containers at the sampler's direction and so forth).

Anything other than the above may invalidate the sample and may be cause for the FDA to reject the sample.

The following information MUST be provided for each lot to be tested PRIOR to dispatch of sampling personnel. This is due to the extensive paperwork that must be completed for the data packages submitted to the FDA.

1. **A copy of the "FDA Notice of Action" form must be provided.**
2. **A copy of the invoice must be provided.**
3. **The commodity being detained and how it is packaged (bulk or specific sized containers).**
4. **The pesticide or microbial issue for which the lot must be tested.**
5. **The street address where the lot is being held, the hours the lot is available for sampling and the name and phone number of the contact person at this location.**
6. **A contact name and phone number, in case the sampler has a problem gaining access for sampling.**

Please note, if necessary to clarify any aspect of the sampling or analytical processes, the FDA may be contacted and sampling will not take place until that clarification is obtained from the FDA.

In order to be removed from automatic detention, a minimum of five (5) consecutive lots must be tested, the actual number of lots to be determined by the FDA, and be within the allowable limits for the pesticide or microbial issue for which it was detained.

Please note, the data packages sent to the FDA include a large amount of information that they require and typically take about 4 days to prepare for pesticide samples and 4 – 8 days for microbiological samples from the time we receive the samples at the laboratory.

PrimusLabs is required to send the results data packages of the detention analysis directly to the FDA, **our results cannot be used by you to move your product**. The FDA and only the FDA can determine if all conditions have been met to release the load currently on hold, and subsequently if all conditions have been met to remove you from automatic detention.

If you have any questions concerning the above, please contact us at (805) 922-0055.