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Dockets Management Branch (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, Md. 20852
Re: Dockets 99D-4488, 99D-4489

December 10, 1999

To Whom it May Concern:

I am writing this letter in regards to the recent release of the FDA guidance on sprouts and its affect on sprout growers in the industry. We, as growers, support the production of safe sprouts and understand the concerns surrounding the industry as a whole. We support enforcement actions necessary to ensure safe sprouts however there are some concerns with the current guidelines.

We are concerned about the time it takes to get results on the microbial testing. We have spoke with different laboratories who have said it is misleading to believe the Salmonella test will present decisive results "in 48 hours or less". The laboratories we spoke with told us it was closer to 72 hours on negatives and longer for presumptive positives. This definitely effects the marketability and available shelf life on the sprouts. The ideal situation would be to get the results back before harvesting the sprouts, which would greatly reduce the risk of contaminated sprouts entering commerce. Perhaps taking the water sample earlier would be acceptable until more reliable rapid tests are developed.

Another concern we have is discarding the entire seed lot in the case of a positive result, as well as a clarification on "entire seed lot". If another grower uses the same lot of seed that we use and does not treat the seed properly or grow them in sanitary conditions, resulting in a positive test result, would this fall under "any other sprout production lots that were made from the same seed lot"? Our position is that it is quite unfair to penalize the grower that used the same seed lot, but took extensive precautionary measures and achieved negative results. These are very serious concerns that would not allow us to confidently place sprouts into commerce, even if all our results are negative. There are also economic concerns since we usually buy seed in large lots. Large lot purchases allow us to thoroughly test the raw seed for pathogens as well as

99D-4488

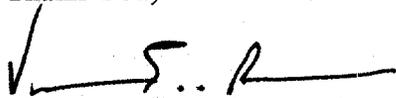
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produce consistent yields. We would not want to risk buying large lots so we would buy in smaller quantities, which costs more and would not be tested as thoroughly. This is a lose / lose situation for the grower and the consumer.

We ask the FDA to consider these concerns and their implications on the industry before the final publication of this guidance.

Thank You,

A handwritten signature in black ink, appearing to read 'V. S. R.', written over a horizontal line.

Vernon Blocker
Quality Assurance Manager