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July 3, 2003

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

RE: Docket No. 02N-0277; Comments on the Proposed Rules for the "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

To Whom It May Concern:

Gate Gourmet, Inc. ("Gate Gourmet") submits the following in response to the FDA Proposed Rules of May 9, 2003, titled "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Gate Gourmet shares the same concerns noted and commented on by the International Inflight Food Service Association ("IFSA") in this matter. However, in support of IFSA's response, we have addressed herein additional components that would significantly impact Gate Gourmet's viability and reasons why the FDA should reconsider the impact of these proposed regulations.

Gate Gourmet Division Americas produces over 100 million meals per year out of its forty-four (44) flight kitchens. Gate Gourmet has performed in-flight catering for over sixty (60) years. In addition to its core business, Gate Gourmet provides catering for the rail industry out of supplemental facilities. These proposed regulations would require a substantial and costly change in the way we deliver and process our meals.

As IFSA stated, there are numerous ingredients included in each meal that is prepared and boarded. Compliance with the traceability regulations depicted in the rule change would require so many re-vamped processes and additional personnel that our organization would likely not recover from the fiscal implications. We would have to completely change the way we produce and package meals for our customers, going to unprecedented lengths to ensure strict batch preparation. A prime example is full meals prepared and package for delivery to our customers. Within our current processes, we could determine shipment origin and location of the entire meal. However, it would be impossible to trace each individual ingredient going into the package. For example, meat from one lot number of ham could be put into sandwiches that are loaded onto numerous flights, compiled with the origins of the other ingredients such as the rest of the make-up of the sandwich, fruit, chips, etc. This level of batch control would make the production of these sandwiches and meals cost prohibitive.

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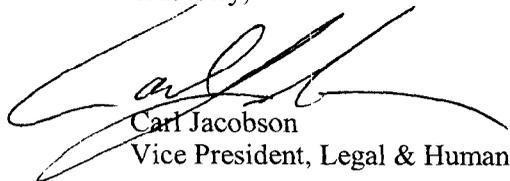
In addition to the feasibility of developing new processes to comply with these regulations, implementing any such methods could require additional training, more employees, new equipment, and additional storage. There are numerous factors to be considered and it should be noted that these regulations require more than the assumed addition of records to address "the new elements" under the current recordkeeping practices. Rather, this will be a monumental task initially and maintaining the records will be exceptionally burdensome. Furthermore, it is unlikely that we and similar businesses will be able to meet the deadline for the compliance period under these circumstances.

This proposed rule change has stated that we as an industry should be included under these regulations due to historical precedence. However, we are regulated very differently than others under the FDA purview and should be considered as an exception to the rule. The rule change seems to depict our industry as a processing plant, producing the same items daily, but in reality, we are more similar to a large restaurant or hotel kitchen, producing a wide variety of meals within a matter of hours. In-flight catering is not regulated under the same rules as a food processing plant because these regulations do not fit our industry. Food in a processing plant may be prepared weeks to a year before consumption. The only difference between our catering and the restaurant service is that our meals are generally consumed 1-4 hours after departing from the kitchen rather than the immediate consumption in the restaurant industry. For this reason, we request the FDA to consider completely exempting the catering industry from the same level of stringency as other industries under the FDA's purview.

Finally, Gate Gourmet asks that the FDA consider whether the air or rail industry can bear the additional burdensome expense of these proposed regulations. As you are well aware, the impact on the airline industry since September 11, 2001, has been tremendous. The airline industry is facing unprecedented times, and the way business is conducted has forever been altered. At best, this is a distressed industry. Reductions and bankruptcy filings by the various airlines have been extreme all over, and continue to deteriorate even 22 months after the September 11 tragedy. These problems have meant immense reductions in the airline catering business. The airlines decisions to significantly cut back, eliminate food service, reduce the load capacity on airplanes and number of flights continue to impact Gate Gourmet's business. It is imperative that these conditions be taken into consideration because it will be most difficult for Gate Gourmet to absorb the costs of these proposed regulations into our current pricing structure. Most likely, we would be forced to pass these costs onto the already struggling airline industry.

Therefore, Gate Gourmet respectfully requests that the air and rail catering industry be considered for exemption under the proposed regulations. Should you have any questions or need clarification of these comments or issues, please do not hesitate to contact me.

Sincerely,



Carl Jacobson
Vice President, Legal & Human Resources

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