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BEFORE THE  
U.S. FOOD AND DRUG ADMINISTRATION  
ROCKVILLE, MARYLAND

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Establishment and Maintenance of Records	)	
Under the Public Health Security and	)	Docket No. 02N-0277
Bioterrorism Preparedness and Response	)	July 8, 2003
Act of 2002	)	

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**COMMENTS OF ATLAS AIR WORLDWIDE HOLDINGS, INC.**

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**COMMENTS OF ATLAS AIR WORLDWIDE HOLDINGS, INC.**

Atlas Air Worldwide Holdings, Inc., parent company of Atlas Air, Inc. (“Atlas”) and Polar Air Cargo, Inc. (“Polar”), is submitting these comments in response to the Food and Drug Administration’s Notice of Proposed Rulemaking, 68 Fed. Reg. 90 (May 9, 2003), concerning record-keeping requirements under the Security and Bioterrorism Preparedness and Response Act of 2002.

Atlas and Polar are separately certificated U.S. air carriers providing cargo air transportation throughout the world. Together, their fleets consist of 51 B747 freighter aircraft. Polar operates a global network of scheduled cargo services, widely held out to the shipping public. Atlas offers some scheduled services but primarily operates dedicated cargo flights for other airlines and airfreight consolidators. Both airlines also provide regular services for the U.S. military.

Atlas and Polar are members of the Air Transport Association (“ATA”) and Atlas is a member of the Cargo Airline Association (“CAA”) – organizations that are submitting general comments on behalf of their members. We are supplementing those comments with these additional views.

Atlas and Polar strongly adhere to the ATA view that protection of our nation’s food supply against credible threats is integrally related to maintenance of the overall security of our nation’s air transportation system. Like other airlines, Atlas and Polar take their security responsibilities very seriously and are working with the Transportation Security Administration, the FAA and Customs as those agencies consider modifications of their own rules. We urge close coordination between the FDA and those other agencies to avoid inconsistent or redundant regulations.

Broadly speaking, the FDA’s proposed record-keeping rule will not create insuperable operational obstacles for Atlas or Polar.<sup>1</sup> As described below, however, we have several areas of concern and urge modification of the proposed rule in certain respects.

The proposed requirement that transporters maintain detailed information about the contents of food shipments (§§1.352(a)(3), (4), (5)) would be exceptionally

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<sup>1</sup> An important reason is that the rule’s applicability is limited to individuals and entities that engage in defined activities relating to “food intended for consumption in the United States.” Proposed §1.326(a). Were it to apply more broadly, the rule would have significant adverse impact.

burdensome and perhaps impossible to satisfy. Nontransporters covered by the proposed rule are the entities with immediate access to that type of information and are separately required by proposed §1.337 to keep it. There is no good reason why transporters also should have to create and retain records containing such information. In addition to being burdensome, proposed §§1.352(a)(3), (4) and (5) are redundant and accordingly should be deleted.

Additionally, under Customs regulations and the current airfreight transportation system, air carriers such as Atlas and Polar typically rely on information obtained from those tendering freight and do not always know that they have food shipments on board their aircraft. For instance, if an air carrier operates a charter flight for a freight consolidator, the applicable air waybills prepared by the consolidator may describe the cargo in general terms without disclosing the presence of food. Therefore, if an air carrier is going to be required to keep records about food shipments, each entity tendering such a shipment to that carrier should be affirmatively required to notify the carrier that food is included and to describe the general nature of the food. For such a requirement to be effective, it would have to extend to freight consolidators in foreign countries, which may not fall within the definition of “foreign facilit[ies].”<sup>2</sup> Alternatively, §1.351 record-

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<sup>2</sup> A “foreign facility” is one (other than a domestic person) that “manufactures/processes, packs, or holds food for consumption in the United States” (emphasis added). It is at least questionable whether a foreign consolidator, which collects and combines freight (including food) for transportation, “packs” or “holds” food.

keeping requirements could be limited to situations in which the transporter has actual knowledge that food is included in the shipment.

Furthermore, the ease or difficulty of record retrieval may vary greatly from one situation to another. Where freight is released to an agent of the consignee, Atlas or Polar would have records about both entities, but not about the trucking company sent by the agent (or the consignee itself) to pick up the freight. To avoid record-keeping redundancy, the FDA should make clear that the entity arranging for truck pick-up – but not the air carrier – is required to keep records about the trucker accepting the freight. If the air carrier is required to provide that information to the FDA, it will require time to obtain the information from the consignee or its agent. Also, the air carrier may require more time than normal to retrieve older records that have been archived at an offsite location.

While the §1.361 requirement for producing records within four hours during the business day and eight hours at night and on weekends may generally be reasonable,<sup>3</sup> some degree of time flexibility needs to be built into the rule to take account of the above situations. This could be accomplished by changing the 4hr./8hr. requirement to a one-business-day requirement. Or the necessary flexibility could be achieved by converting §1.361 to §1.361(a) and adding a new §1.361(b), reading as follows: “The time

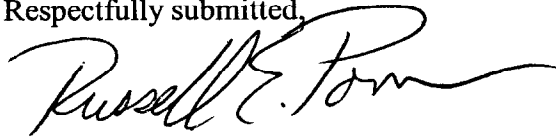
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<sup>3</sup> When old records have been requested, it is hard to understand the need for production within four or eight hours, as the case may be.

requirements of §1.361(a) shall be inapplicable when the requestee reasonably determines, in consultation with the FDA, that strict compliance with such requirements is not practicable or when the FDA determines that it does not need the records in such an expeditious fashion. In such circumstances, the requestee shall produce such information as soon as practicable.”

Finally, we suggest adding a §1.327 exclusion that covers persons who transport food for the U.S. military and U.S. government agencies with respect to that food. Those entities are sophisticated and able to establish their own requirements. Transporters of food for those entities should not be subject to potentially duplicative FDA standards.

Respectfully submitted,



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