BEFORE THE UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

GLYCINE FROM CHINA, INDIA, JAPAN, AND THAILAND
INV. NOS. 701-TA-603-605 AND 731 TA-1413-1415 (FINAL)

TESTIMONY OF MICHAEL LISH SENIOR VICE PRESIDENT AJINOMOTO HEALTH AND NUTRITION NORTH AMERICA INC.

Mr. Chairman, Members of the Commission, my name is Michael Lish, and I am the Senior Vice President of Ajinomoto Health and Nutrition, North America Inc. I manage our Amino Science Division in Raleigh, North Carolina and have worked in Ajinomoto's amino acid business for 28 years. Of the 3,000 jobs that Ajinomoto supports in the United States, 400 are associated with manufacturing facilities that depend on glycine as a key input.

Put simply, Ajinomoto's U.S. manufacturing facilities require ultra-pure, certified glycine that the U.S. industry does not provide. We are happy to partner with U.S. producers and have a longstanding relationship with Chattem, but for certain amino acid applications we require imported material because Petitioners GEO and Chattem thus far cannot support our needs.

Ajinomoto Health and Nutrition uses glycine in amino acid mixtures meant for intravenous solutions. At our facilities in Illinois and North Carolina, we mix glycine with other amino acids to produce a complex, engineered product that

downstream pharmaceutical and healthcare companies use in manufacturing lifesaving IV solutions in the United States for sale worldwide. Intravenous solutions have a broad range of medical and therapeutic applications, from delivering hydration or antibiotics to replacing a solid diet for patients with weakened digestive systems. We are committed to U.S. manufacturing and recently consolidated the production of the amino acid mixtures at issue in the United States after closing our European facility.

Because IV solutions are delivered directly to the bloodstreams of human patients, purity and quality control are of extreme importance. We and our U.S. healthcare customers are not in a position to compromise safety or quality in intravenous solutions for human patients in ways that could put patients at risk. The companies that manufacture intravenous solutions in the United States - our customers - are subject to rigorous regulatory standards in the United States and European Union that require glycine that is approved for use as an active pharmaceutical ingredient in IV solutions. Our products are principally regulated by the U.S. Food and Drug Administration and by the European Directorate for the Quality of Medicines and HealthCare, as our customers operate in both the United States and the EU. Many other governments around the world mirror U.S. or EU standards. Certain of our customers also maintain their own quality and qualification requirements, which are often more demanding than regulatory

standards or track the regulatory standards of a different jurisdiction so as to permit sale in global markets. For instance, a customer in the EU might require that a product meet a certain FDA specification in order to ensure that the product satisfies the customer's own high standards and commitment to exemplary patient care, and to permit sale in the United States or in countries that track FDA standards.

Obtaining a certification from the FDA or EDQM can take three or four years at either agency, and it can be costly for producers to maintain certifications once they've acquired them. The FDA, for example, is vigilant in inspecting the facilities of producers of active pharmaceutical ingredients, and it requires that producers maintain extensive records demonstrating the integrity of their product. There's a lot at stake, including the health and safety of tens of thousands of patients.

Unfortunately, no U.S. producer offers glycine that is approved for use as an active pharmaceutical ingredient in IV solutions by the U.S. FDA, EDQM, and our IV customers.

Consistent with Ajinomoto's commitment to its U.S. manufacturing facilities, we would like to produce amino acid solutions domestically that can be used to care for patients in the United States and other parts of the world, including the EU. Having multiple qualified suppliers for a key ingredient, including one

located in the United States, would make our lives a lot easier. But, because no U.S. producer provides dual-certified glycine for IV use, it is difficult for us to produce a mixture in the United States using U.S. glycine that we can provide to our customers with global operations. We have a longstanding relationship with Chattem and have approached them about pursuing EDQM certification. Thus far, Chattem has not done so, which means our only solution is to use imported glycine from Japan. For this reason, the imposition of antidumping duties on imports of dual-certified glycine would accomplish nothing, except driving up our costs, as well as those of our U.S. health care customers who make intravenous solutions for the global market. No matter what dumping duties are imposed, we and our customers are not in a position to use uncertified glycine in intravenous solutions that will be administered to human patients around the world. Instead, such duties would threaten our ability to expand our U.S. manufacturing of amino acid solutions for pharmaceutical use and the ability of our customers to support a skilled American workforce to manufacture an important healthcare product.

Japanese producers, in contrast, can and do offer ultra-pure product that carries active FDA, EDQM, and IV customer certifications. As a result, Japanese glycine is unique in that we can sell an amino acid mixture for IV use containing Japanese glycine in the United States, EU, and other markets. An amino acid mixture containing U.S. glycine, on the other hand – even if it is pharmaceutical

grade – could not be sold for IV use in both the United States and EU, *period*, because of GEO's and Chattem's lack of dual certification.

GEO and Chattem say that "glycine is glycine is glycine." This may be the case for mouthwash and deodorant. But, the glycine we use is ultimately going to hospitals for injection directly into patients. Even trace amounts of impurities like aluminum can accumulate to toxic levels when they enter intravenously. From our perspective, calling all glycine interchangeable and implying that we should put uncertified glycine with higher levels of impurities into healthcare products for sale in the EU and other overseas markets would be irresponsible. We and our U.S. healthcare customers are committed to the health, safety, and well-being of patients around the world, and we hope that Petitioners would join in this commitment.

To put into perspective how pure we need our glycine to be, FDA regulations require that IV solutions have at maximum 25 *micrograms* per liter of aluminum. This is an extraordinarily small amount of trace aluminum. For instance, if you poured two 12 ounce cans of soda into a reservoir of water the size of the Lincoln Memorial Reflecting Pool, it would then have too many trace impurities to meet the specification. And this is just aluminum – Ajinomoto alone tests for dozens of additional requirements in any glycine that it sources for IV use, including iron, arsenic, ammonium, mold, and other impurities. Again, because this glycine is destined for medical care, quality and certifications are more

important purchasing factors than anything else, including saving a few cents by switching suppliers.

We are grateful for the Commission's examination of this important industry and for its commitment to supporting U.S. trade, manufacturing and jobs. We wish, however, that the U.S. industry could demonstrate similar commitment to our country's IV pharmaceutical needs and export competitiveness. While we would welcome an opportunity to source glycine domestically, the U.S. industry's inability to serve these needs forces us to secure alternative sources of supply for this crucial ingredient. As such, imposing punitive duties on dual-certified glycine would threaten U.S. manufacturing and jobs and put U.S. manufacturing and exports of intravenous solutions at risk. Thank you for your time and attention; I'd be happy to answer any questions.