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June 2, 2003

Food and Drug Administration
Ms. Shellee Anderson
Center for Food Safety and Applied Nutrition
5100 Paint Branch Pkwy
College Park, Maryland 20740

Re: Reopening of Comment Period for Infant Formula Products

Dear Ms. Anderson,

In reading the supplementary information posted in the Federal Register /Vol. 68, No 81, I noticed that it was mentioned several times about the safety of infant formula products. One area that has failed to receive proper attention is the health concerns regarding the tremendous growth of the underground market in trafficking of infant formula products (specifically the contracted formula). WIC contract formula represents approximately 75% of the infant formula stolen, due to its resale value and the ability to easily fence the product due to demand and it carries a specific dollar value.

The underground market is effectively controlled by organized crime. In Texas and other states several of the groups have been thought to have terrorist links. Organized crime generally uses illegal aliens to conduct the actual "boosting" or stealing of products from the stores and then the products are laundered or fenced back into the market through smaller retail stores, flea markets, and in some cases, specialty stores like "WIC-Only" stores. Generally, these types of locations can't compete with the larger food retailers on price with legitimate distribution sources. It is estimated that in Texas alone, retailers lost \$4.5 million last year in stolen infant formula products and it is increasing at an alarming rate. It is estimated that for Texas babies on WIC, this represents about 1,400,000 days of feedings. This is their sole source of nutrition and the infant formula products distributed through the underground market are not stored in licensed or inspected storage areas, not maintained in climate controlled area's, have no pest or rodent controls, and are distributed back into the market by unlicensed suppliers over the Internet, through Flea Markets, or to small neighborhood stores or at specialty stores like WIC-Only stores. The opportunity for these products to be tainted, contaminated, diluted or tampered with is a real threat to the most valuable and vulnerable citizens of our country -- our babies.

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At no level involved with the underground market is the quality of the product, accuracy of the dates or labeling taken into consideration that this product meets the nutrition qualities that our babies are dependent on. In Texas last year, approximately 50% of the babies born were enrolled in the WIC Program. It is estimated that over 60% of the infant formula product sales are directly related to the WIC Program.

We recommend that steps be taken immediately to determine the size of the underground market dealing in infant formula products. We also recommend that a study be undertaken to determine the impact of price rebates back to state programs on contracted formula products regarding price of the products, development of the underground market and the health concerns it poses and potential alternative funding sources for the state programs in place of the rebate on infant formula products.

We believe that approximately 5% of all contract infant formula sales are of products that have been stolen and the nutritional value of the product has been compromised.

We organized a Task Force in Texas to research and develop workable solutions to the problems in Texas. The Task Force is comprised of representatives from Texas Department of Health (both Food and Drug Safety and Bureau of Nutrition Services); Texas Comptrollers Office; Texas Department of Human Services; Texas Department of Public Safety; Office of the Attorney General; USDA Food and Nutrition; USDA Office of Inspector General; retailers and retailer representative associations; advocacy groups and other interested parties like local law enforcement groups.

One of the conclusions reached is that we would like to see FDA recognize the problem and then mandate that manufacturers of infant formula products develop workable solutions, for example, other types of containers that would allow the use of sensor tagging devices. It is important to be able to track the path of the products to ensure quality of product.

In Texas our Task Force has proposed bills that are being considered by our legislature that would increase penalties and limit the ability to store food products (including infant formula) in unlicensed storage facilities or to traffic products by unlicensed distributors. Our state agency administering the WIC Program has changed its contract with its WIC vendor community to make it illegal to purchase infant formula products from unauthorized wholesaler/distributors. Some retailers have relocated the product under lock and key even though this creates a hardship on our customers. Others have tried stamping the name of the retailer on the cans but this adds unnecessary cost. We believe there isn't one easy solution to address the problem but a multiple number including the ability to source-tag the containers.

We appreciate the opportunity to send our comments and appreciate your time and consideration. If we can be of any help or offer any more explanation, please let us know.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Williams". The signature is written in a cursive, flowing style.

Joe Williams

President

Gulf Coast Retailers Association, Inc.