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Client Advisory

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COMING SOON: NEW BIOTERRORISM RECORDKEEPING REQUIREMENTS!

-- New Rules to Apply to Food Distributors, Manufacturers and Transporters --

In a recent move by the U.S. Food and Drug Administration ("FDA") to enhance food safety, the FDA has proposed regulations requiring domestic and foreign food businesses to establish and maintain records. The proposed regulations affect almost all operations that manufacture, process, pack, transport, distribute, hold, or import food, and could be finalized as early as March 2004.

These new regulations complement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002. At that time, the FDA enacted food safety regulations requiring many domestic and foreign food businesses to register their operations.

The new required records must adequately identify the specific source of each ingredient used to make every finished product. All required records should contain:

- the immediate previous source of all foods received and the recipients of all food released, along with contact information for companies and individuals;
- the type of food, including brand name and specific variety; and

- contact information for transport companies and their agents who brought the food or took it away.

Records must be created when the food is received, released, or transported, and must be retained for two years in the case of most foods.

While the rules are not due to be finalized until March, certain provisions regarding access to records and other information are already in effect and compliance is required. Failure to create and retain the records required by the FDA's proposed rule could result in civil or even criminal punishment.

The FDA's proposed recordkeeping rule is relatively complex. Many companies will be governed by the new requirements, and proper compliance is a must. If you have any questions, please feel free to contact Terence J. Fox, Esq., of Archer & Greiner's Corporate Department at (856) 795-2121.

For information about a seminar addressing the significant recordkeeping requirements of the Bioterrorism Act, contact Karen Kruza at 856-616-2691.