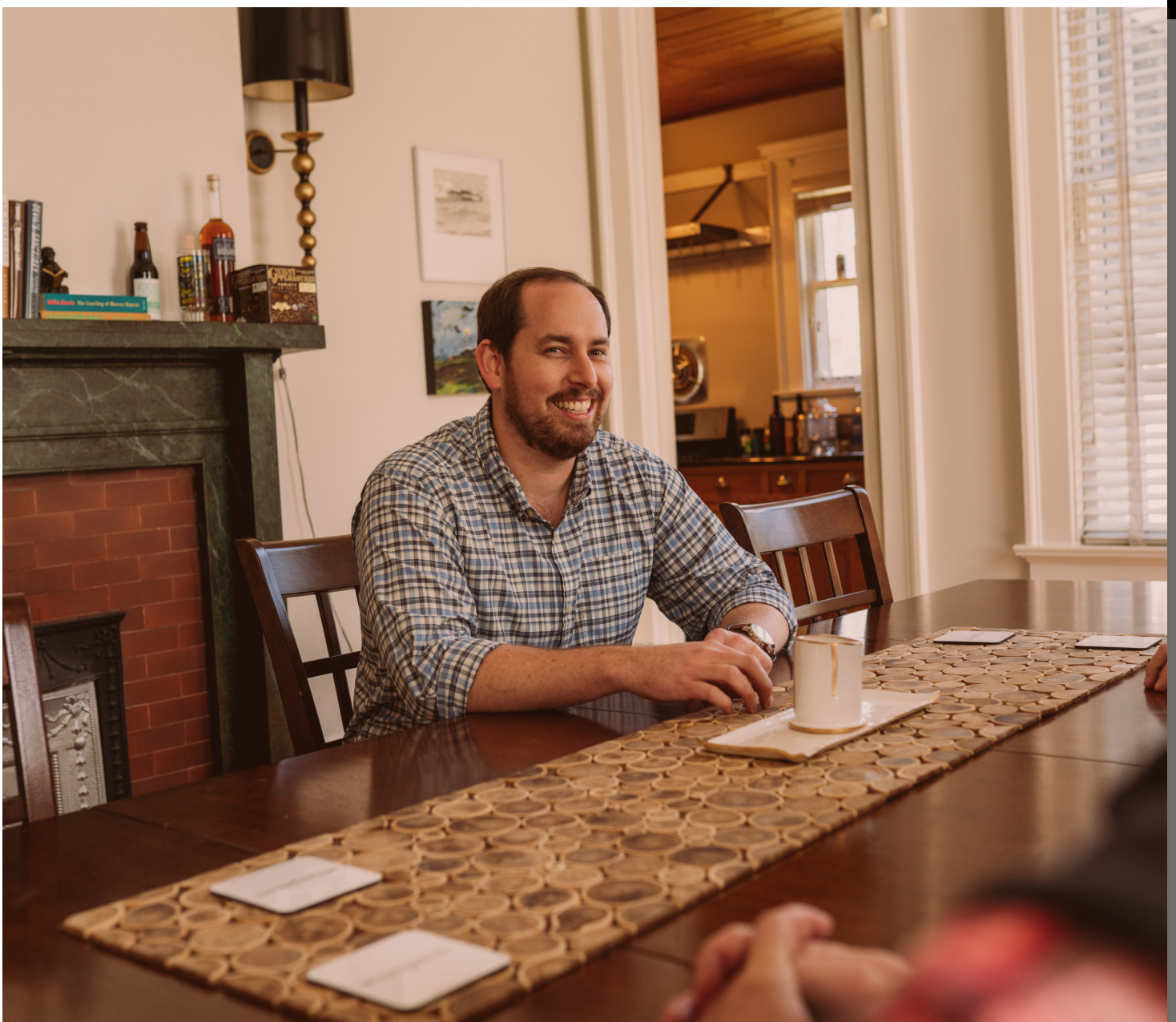
FDA FOOD REGULATIONS

The Food and Drug Administration (the “FDA”) is responsible for ensuring that the United States food supply is safe, wholesome, sanitary and properly labeled. The FDA regulates the production and supply of food products through the Food, Drug and Cosmetic Act (the “FDCA”) and related rules and regulations.



FDA FOOD REGULATIONS

The FDA has rules and regulations related to:

- When businesses that produce or sell food products must register with the FDA;
- The kinds of records food businesses must keep;
- Good manufacturing practice requirements for businesses that produce food products;
- How manufacturers and distributors must label food products;
- Food safety and preventive controls;
- The FDA's power to inspect facilities where food is processed, packed or held; and,
- The importation of food.

Parties that violate federal laws and regulations for food production and distribution can face severe civil and criminal penalties and lose the ability to distribute food products.

FOOD FACILITY REGISTRATION REQUIREMENTS

The owner, operator or agent in charge of any domestic or foreign facility (food facility) must first register the food facility with the FDA before it manufactures, processes, packs, holds or imports food for human consumption in the United States.

When registering a food facility with the FDA, a party must provide: the food facility's name, address and phone number; if the food facility is a subsidiary, its parent company's name, address and phone number; the names, addresses and phone numbers of the owner, operator and agent in charge; for a foreign food facility, the name, address, phone number and the emergency contact phone number of the foreign facility's United States agent; for a domestic food facility, an emergency contact phone number; all trade names the food facility uses; any applicable food product categories; certification that the information the food facility has submitted is true and accurate; and, an assurance that the food facility will give the FDA access to the facility for inspections.

A food facility must renew its registrations every other year. If a food facility does not register with the FDA, renew its registration or otherwise comply with the registration requirements, it is in violation of the FDCA.

Certain businesses are exempt from this requirement, including: farms; retail food establishments; restaurants; nonprofit food establishments where food is prepared for or served directly to consumers; and, facilities that are regulated exclusively throughout the entire facility by the United States Department of Agriculture (the “USDA”).

SUSPENSIONS

The FDA's registration requirements provide the agency with information about the origin and distribution of food products, which can help the agency respond to actual or potential threats to the food supply. One way the FDA responds to these threats is by suspending a food facility's registration. When the FDA suspends a food facility's registration, parties are prohibited from: importing or exporting food into the United States from that facility; offering to import or export food into the United States from that facility; and, introducing, in any way, food into interstate or intrastate United States commerce from that facility.

The FDA can suspend the registration of any food facility that: created, caused or was otherwise responsible for a reasonable probability of food causing serious adverse health consequences or death; or knew of, or had reason to know of, a reasonable probability of food causing serious adverse health consequences or death.

RECORDKEEPING REQUIREMENTS

The FDA has detailed recordkeeping requirements for domestic and foreign parties that manufacture, process, pack, transport, distribute, receive, hold or import food in the United States. These parties must: establish and maintain certain records related to their role in the food supply chain; and, provide the FDA with access to certain records on the agency's request.

These requirements help the FDA to identify the immediate: previous sources of food handled by a party and subsequent recipients of food handled by a party. This information can be crucial when the FDA is trying to minimize the impact of a food source that it has determined to be adulterated or unsafe under federal standards.

Similar to the FDA's registration requirement, certain businesses are generally exempt from the recordkeeping requirements, including: farms, restaurants, parties that distribute food directly to individual consumers, retail food establishments that employ ten or fewer full time employees, and parties that manufacture, process, pack, transport, distribute, receive, hold or import food that is within the USDA's exclusive jurisdiction.

MAINTENANCE OF RECORDS

Parties involved in the production and distribution of food must maintain certain records related to their business. The FDA requires different records for:

- Transporters. These are parties who either: have possession, custody or control of an article of food in the United States for the sole purpose of transporting the food; or are foreign and transport food in the United States.
- Nontransporters. These are parties who own food or who hold, manufacture, process, pack, import, receive or distribute food for purposes other than transportation.

However, under the FDCA neither transporters nor nontransporters are required to maintain (and the FDA may not demand access to) records relating to food recipes, financial data, pricing data, personnel data, research data or sales data.

TRANSPORTER RECORD REQUIREMENTS

Transporters must maintain records that would help the FDA identify the immediate previous sources and subsequent recipients of food products. This generally includes records describing: the names of the transporter or nontransporter: from whom the transporter received the food; and to whom the transporter delivered the food; the food's origin and destination points; the date the transporter received and released the shipment; the number of packages; a description of the freight; the food's shipping route; and, the transfer points through which the shipment moved.

NONTRANSPORTER RECORD REQUIREMENTS

Nontransporters must also maintain records that would help the FDA identify the immediate previous sources and subsequent recipients of food products. This includes records describing:

- The name, address, telephone number and, if available, the fax number and e-mail address of the domestic or foreign nontransporter that: had the food before transferring it to the current nontransporter; and later acquired the food from the current nontransporter.
- An adequate description of the food the nontransporter received and released, including the brand name and specific variety.
- The date the nontransporter received and released the food.
- For persons who manufacture, process or pack food, the food product's lot or code number or other identifier.
- The name, address, telephone number and, if available, the fax number and e-mail address of the transporter that: delivered the food to the nontransporter; and took the food from the nontransporter.
- Information about the quantity of food and how it is packaged.

FDA ACCESS TO RECORDS

The FDCA and related regulations authorize the FDA to access and copy a party's records on request. A party must provide the FDA with access to its records if the FDA either: has a reasonable belief that a food product: is adulterated; and presents a threat of serious adverse health consequences or death to humans or animals; or believes that there is a reasonable probability that the use of or exposure to an article of food will cause serious adverse health consequences or death to humans or animals.

A record request from the FDA can be based on various events, including foodborne outbreaks, food product recalls, adverse event reports or consumer complaints. Under these circumstances, the FDA can access and copy any record that relates to the manufacture, processing, packing, distribution, receipt, holding or importation of the food at issue.

If a party refuses to grant the FDA access to appropriate records, the FDA can initiate criminal or civil proceedings. The FDA can also refuse admission of food offered for import into the United States.

GOOD MANUFACTURING PRACTICE REQUIREMENTS

Under the FDA's Current Good Manufacturing Practice regulations (“CGMP”s), food that is offered for sale or introduced into interstate commerce must be produced under safe and sanitary conditions. The CGMPs outline the FDA's manufacturing recommendations and requirements for producing processed food, including the: requirements for the maintenance, layout and sanitary operations of food processing buildings and facilities; standards for the design, construction and maintenance of equipment and utensils; general sanitation production and process controls for ensuring that food is safe for human consumption; and, general requirements for warehousing and distribution. The CGMPs requirements are described generally, which gives manufacturers some flexibility in how they implement them.

Under the CGMPs, the FDA can also establish the maximum defect action levels (“DAL”s) for a defect (such as the presence of mildew, rot, mold, insect parts or rodent filth) that is natural or unavoidable even when foods are produced according to the federal manufacturing standards. These defects generally do not present a hazard to consumer health. However, a party can still face enforcement actions for adulterated food if it uses poor manufacturing practices, regardless of the DALs.

FOOD PRODUCT LABELING

Food products that move in interstate or foreign commerce must be properly labeled. Under the FDCA and the Fair Packaging and Labeling Act (the “FPLA”), food manufacturers and distributors: must include certain information about a product on its label and principal display panel, including specific nutritional information and a list of major food allergen ingredients; and are prohibited from making certain claims on labels and misbranding food. The FDA does not pre-approve food labels subject to its regulations. Instead, it relies on enforcement actions, warning letters and other measures to correct misbranded products.

FOOD SAFETY AND PREVENTIVE CONTROLS

The Food Safety Modernization Act (the “FSMA”) amended the FDCA and gave the FDA more authority to create rules to strengthen the United States food safety system. The FSMA and FDCA address, among other things: the efforts that food facilities must take to prevent food safety issues; and, FDA inspections and how the agency can respond to food safety issues.

PREVENTIVE CONTROLS

In response to the FSMA, the FDA has changed its handling of food safety by focusing more on preventing food safety issues instead of simply responding to them after the fact. The FSMA amended the FDCA to require comprehensive, prevention-based controls across the food supply. Among other things, a food facility now must: evaluate the hazards that could affect food that is manufactured, processed, packed or held at its facility; identify and implement preventive controls to minimize or prevent these hazards; prepare a written plan that documents and describes the food facility's hazard analysis and preventive controls; monitor the performance of its preventive controls; maintain routine records of its monitoring activities; and, provide assurances that its food products are not adulterated or misbranded.

Under the FSMA, the FDA also must: establish science-based minimum standards for the safe production and harvesting of fruits and vegetables and issue regulations to protect against the intentional adulteration of food.

INSPECTION AND COMPLIANCE

The FSMA broadens the FDA's ability to inspect food facilities and ensure compliance with federal laws and requirements. The FSMA: establishes a mandatory inspection frequency for food facilities, based on risk; gives the FDA authority to access and copy a food facility's records; and, mandates that certain food testing be done by FDA accredited laboratories.

If the FDA discovers that a food producer is violating the FDCA or that a food source is unsafe, it can take actions to remedy the problem. The FDA can, among other things: administratively detain adulterated or misbranded food; suspend a food facility's registration and prohibit it from distributing food; issue a mandatory recall of adulterated or mislabeled food; or initiate criminal or civil proceedings against noncompliant parties.

IMPORTING FOOD PRODUCTS

The FDA regulates not only food produced domestically, but also the millions of food products imported into the United States every year. Food imported into the United States must comply with the same federal laws and standards as food produced in the United States. This includes, for example, nutrition labeling requirements, unless the food product qualifies for an exemption.

The FSMA and FDCA also create additional requirements for parties that import food into the United States or produce food abroad for eventual export to the United States. For example:

- Importers must generally: verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe, unadulterated and not misbranded; and give the FDA prior notice before food is imported or offered for import into the United States.
- The owners, operators or agents in charge of foreign facilities must allow inspections by United States inspectors or their representatives.

The FDA can also require additional safety certification for imported food based on certain risk criteria, including: any known safety risks associated with the food; any known food safety risks associated with the country, territory or region where the food originated; and, if the FDA determines that the food safety programs, systems and standards in the country, territory or region where the food originated are inadequate to ensure that the food is as safe as a similar article of food that is manufactured, processed, packed or held in the United States.