

FDA Background

The U.S. Food & Drug Administration (FDA) is responsible for protecting public health by regulating human drugs and biologics, animal drugs, medical devices, tobacco products, food (including animal food), cosmetics, and electronic products that emit radiation. FDA does have authority to inspect regulated facilities to verify that they comply with applicable good manufacturing practice regulations. **However, FDA does not “approve” health care facilities, laboratories, or manufacturers. FDA does not certify or approve building products.**

USDA Background

The U.S. Department of Agriculture (USDA) provides leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on public policy, the best available science, and effective management. The USDA is responsible for maintaining the safety of, and inspecting, agricultural products such as grain, meats, and dairy products. **However, the USDA does not inspect facilities (leaving that to the FDA) nor does the USDA certify or approve building-related products.***

The Building Products Connection

When inspecting food or pharmaceutical related facilities under their charge, the FDA looks for Current Good Manufacturing Practices (CGMPs). CGMPs provide systems that assure proper design, monitoring, and control of manufacturing processes and facilities. This formal system of controls, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. Accordingly, such factors as the cleanliness of equipment as well as the surroundings, become important.

Therefore, building products can contribute to good manufacturing practices and help ensure a safe food and drug supply. FDA inspectors and savvy facility owners look for building products that are easy to clean and do not permit the buildup of dirt, microbes, bacteria, etc.

Special-Lite Compliance with Best Practices

Special-Lite manufactures world-class engineered architectural solutions. **Our products are designed and produced in a manner making them appropriate for use in food and drug production facilities. The very construction of these products contributes to such use.**

Consider our aluminum/FRP hybrid doors. These flush doors are highly resilient and can contribute to such facilities from a perspective of both appearance and hygiene. Our FRP (fiber reinforced polyester) face sheets naturally resist smudging or other appearance issues. And such innovations as our SpecLite 3® coating on our most popular door, the SL-17, provide for super easy cleaning.

Further, we manufacture all fiberglass doors such as our popular AF-100 and AF-200 doors. The construction of these doors creates a monolithic structure, hermetically sealed and immune to moisture and corrosive gasses or liquids. The resin used in the fiberglass production also complies with all regulatory requirements of the FDA cGMP. Likewise, the finish on these doors makes for easy cleanup.

Pair either our hybrid doors or all fiberglass doors with our fiberglass framing to create a complete system contributing to the appearance and hygiene of the production facility. The sealed and pultruded fiberglass components are chemically welded at joints and make an ideal substitute to hollow metal frames which are subject to corrosion and other appearance and hygiene issues.

The following chart summarizes Special-Lite products ideal for interior use at food and drug production facilities. All Special-Lite doors and frames are appropriate for entrance solutions for these facilities.

	Smooth Pultruded Fiberglass Door AF-100	Smooth Composite Fiberglass Door AF-200	Pebble Grain Composite Fiberglass Door AF-217	Sandstone-Texture Composite Fiberglass Door AF-220	Pebble Grain FRP Hybrid Door SL-17	Sandstone-Texture SL-20
Flush Door	X	X	X	X	X	X
Easy to Clean	X	X	X	X	X	X
Through-Color Face Sheets			X	X	X	X
SpecLite 3® Surface Seal			X		X	
Sealed Monolithic Structure	X	X	X	X		
Factory-Applied Painted Finish	X	X				
Fire Door Model Available		X	X	X	X	X
Flush Vision Panel	X	X	X	X	X	X
Privacy Flush Vision Panel	X	X	X	X	X	X

**Among the many agencies which comprise the USDA is the Agricultural Marketing Service (AMS). As part of their outreach for strategic marketing of agricultural products, AMS/USDA does provide for the "acceptance" of products. Such acceptance can take the form of Dairy Acceptance or Meat & Poultry Acceptance. Special-Lite is currently pursuing such acceptance for our products. Still, this does not represent a product certification from the USDA.*