FDA- Food and Drug Administration

What is the meaning of FDA?

The **Food and Drug Administration** is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

What does the FDA regulate?

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.

What foods are FDA approved?

The agency regulates all foods and food ingredients introduced into or offered for sale in interstate commerce, except for **meat, poultry, certain processed egg products, and catfish**, which are regulated by the U.S. Department of Agriculture.

Does FDA apply in India?

Established in November 2008, the India Office serves as the lead FDA on-site presence in India. The mission of the New Delhi-based office is to help ensure the safety, quality, and effectiveness of medical products and food produced in India for export to the United States. India is one of the largest exporters of drugs and biologics to the United States, as measured by FDA import lines. The country is also a global leader in the export of shrimp and spices.

The India Office seeks to accomplish these objectives by:

- Conducting commodity-specific inspections to meet the requirements of FDA-specific legislative mandates;

- Building strong coalitions and partnerships with regulatory authorities, industry, academia, multilateral organizations, non-governmental organizations, and other relevant institutions to increase the FDA's understanding of India's regulatory framework and processes, and to share information about FDA science-based regulations and requirements;

- Enhancing FDA's knowledge of India's legal requirements and oversight capacity of India's regulatory agencies; Indian companies that manufacture or export products subject to the FDA's jurisdiction; and emerging trends and issues of relevance to the FDA to ensure product safety and quality; and

- Expanding upon and building better quality data to inform the FDA's regulatory decisions and actions.

Is FDA approval required in India?

The food products do not require FDA Certification, but the food facilities are required to get registered with the FDA. The product, before being distributed in the United States, does not require any kind of certification from the FDA. The FDA officials visit and check the food and pharma plants facilities in India.

What are the Benefits of FDA Certification?

- **Impact Within The Industry**

  FDA necessities are rigorous, and a product frequently takes a long time, a sequence of iterations and testing to get a ultimate FDA approval, but once you get it, this product will offer a major impact in the direction of the benefit of the consumer as it will be available for purchase, thus enhancing the lives, conditions, and health of your target market.

- **In-Demand Product**

Products that have FDA-approval rapidly move up the position in terms of demand. Consumers recognize it has been tested, and it's secure to use. Consequently, the demand for your product will boost up. Having the FDA's seal of approval is habitually a matter of a need, relatively than a nice object to have.

- **Access To Worldwide Markets**

  FDA approval for your product also means you get a Certificate of Foreign Government (CFG). With this, you can essentially open up your deals points to initiate selling to countries like Japan, Brazil, Australia, & China. This displays other countries that your product has been FDA approved, and it can be marketed & exported from the United states of America.

- **Increase Credibility**

  FDA is known globally, and it has acquired its own brand status. FDA has a unwavering principle and a long list of strategy to help a company achieve and get FDA approval. If your product gets the FDA approval that means it has been through meticulous product quality testing & various enhancement practices before being submitted to the FDA for evaluation.

- **Expand Your Company's Expertise**

  Once you achieve FDA approval, it will make it a lot easier for your company to expand into other areas of business. Once your product has achieved FDA status, the next thing you'll need to do is continuously update, upgrade, and enhance your product, which can also mean moving into other industries.

- **Enhanced Idea To Advance The Product**

It’s about having more understanding of building a quality product right from the creation, design, testing, & production. Fundamentally, every single step of the way, it's all about exhibiting safety & efficacy concerns.

- **Creates Lines For Funding**

  The good thing about FDA approval is you get to have to easier access to funding. FDA clearance displays that the product manufacturer is a stern and approved manufacturer. Big companies are for all time on the lookout for smaller companies in requirement of funding to add to their collection of products.

- **Acknowledged In Medical Networks**

  A food or medical product will only be entertained by medical facilities and hospitals only if it has an FDA clearance. Without it, you can’t even sell your products in pharmacies. When building your product, you're bound to be working with medical facilities to do clinical trials, pilot testing, or usability devices. This is a great way to increase and expand your network.

TABLE 1. MILK AND DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Milk Powders (e.g. whole, nonfat or filled milk, buttermilk, whey & whey protein concentrate) (intended for children more than 36 months of age and adults)	*Salmonella*/25g, normal routine	10	0	0	
	for high risk population	30	0	0	
	SPC/APC, cfu/g	5	2	$5x10^3$	$5x10^4$
	Enterobacteriaceae cfu/g	5	1	10	10^2
Sweetened Condensed Milk	[1]Coliforms, cfu/g	5	1	10	10^2
	Yeast and Molds Count, cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	1	10^3	10^4
Liquid Milk (evaporated or ready to drink) **& Cream** (UHT/sterilized)	Commercial Sterility	6	0	Commercially sterile	
Pasteurized Milk	[2]Coliforms, cfu/mL	5	1	10^2	10^3
	Salmonella/25mL	5	0	0	
	Listeria monocytogenes/25 mL	5	0	0	
	Psychrotrophic bacteria, cfu/mL	5	1	10	10^2
	SPC/APC, cfu/mL	5	1	$5x10^4$	10^5
	➢ for flavored milk	5	2	$5x10^4$	10^6
Pasteurized Cream	[1]Coliforms, cfu/g	5	1	10^2	10^3
	Salmonella/25g	5	0	0	
	Listeria monocytogenes/25g	5	0	0	
	Psychrotrophic bacteria, cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	1	$5x10^4$	10^5
Yogurt and other fermented milk	*S. aureus* (coagulase +), cfu/mL	5	2	10	10^2
	[1]Coliforms, cfu/mL	5	2	10	10^2
	Salmonella/25mL	5	0	0	
	Lactic Acid, cfu/mL (required minimum level: $\geq 10^6$)	-	-	-	-

[1] Coliforms must be negative for *E. coli*

Legend: n – number of sample units selected from a lot of food to be examined
m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP
M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
c – maximum allowable number of defective or marginally acceptable units