

FDA & FPO (India)

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FDA

- The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- The Pure Food and Drug Act of 1906 was the first of more than 200 laws that constitute one of the world's most comprehensive and effective networks of public health and consumer protections.

Here are a few of the congressional milestones:

- **The Federal Food, Drug, and Cosmetic Act of 1938** was passed after a legally marketed toxic elixir killed 107 people, including many children. Among other provisions, the law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections.
- **The Kefauver-Harris Amendments of 1962**, which were inspired by the thalidomide tragedy, strengthened the rules for drug safety and required manufacturers to prove their drugs' effectiveness.
- **The Medical Device Amendments of 1976** followed a U.S. Senate finding that faulty medical devices had caused 10,000 injuries, including 731 deaths. The law applied safety and effectiveness safeguards to new devices.
- **The Family Smoking Prevention and Tobacco Control Act** (Tobacco Control Act) was enacted in 2009, giving FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.
- Today, the FDA regulates \$1 trillion worth of products a year. It regulates all foods and food ingredients introduced into or offered for sale in interstate commerce except for meat, poultry and some egg and catfish (which are regulated by USDA); ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and cellular and gene therapy products), medical devices, and animal drugs and feed; and makes sure that cosmetics and medical and consumer products that emit radiation do no harm.

FDA Standards Program

- Participation in the development and use of standards is are integral to the execution of FDA's mission to protect and promote the public health.
- Standard-setting activities include:
 - material specifications
 - testing methods
 - manufacturing practices
 - product standards
 - scientific protocols
 - the development of performance characteristics
 - compliance criteria
 - labeling
 - other technical or policy criteria

INO

- 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.
- Established in November 2008, the Office of Global Policy and Strategy's (OGPS) India Office (INO) serves as the lead FDA on-site presence in New Delhi, India.
- The India Office addresses operational and policy matters concerning FDA-regulated products in collaboration with the Government of India counterparts.
- In line with the FDA's mission, the INO's primary focus is ensuring the safety, quality, and effectiveness of food and medical products exported to the United States.

CDSCO

- A large amount of the pharmaceutical products that are imported into the United States are manufactured in India. Accordingly, FDA's presence in the country has steadily increased over the past several years. Lately, the [number of FDA warnings being issued to Indian companies has grown significantly](#), resulting in an increase in the collaboration between Indian and U.S. regulators.
- For the past few months, individuals from [FDA's India office](#) have been partnering with the Indian government's [Central Drug Standards Control Organization](#) (CDSCO), "to share inspectional techniques and guidance for conducting current good manufacturing practices of pharmaceutical facilities."
- As part of this partnership, there have been training sessions held in Ahmedabad and Bengaluru, India for about 200 CDSCO regulators and some of the State drug control agencies.
- FDA stated that "it was clear from the interactions that the Indian inspectors had extensive knowledge of FDA and of the international techniques for conducting inspections." In addition, U.S. representatives expanded their knowledge on the differences between FDA and Indian legislation and regulations.
- Furthermore, the Agency has declared that individuals from the FDA and the Government of India will continue to work together, leveraging each others knowledge and strengths to ensure [patient safety](#) in India and [product quality of FDA-regulated pharmaceuticals](#). It will certainly be interesting to see where this partnership takes the U.S. pharmaceutical industry in the future.

***The Central Drugs Standard Control Organisation(CDSCO)** under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices, four sub zonal offices, thirteen Port offices and seven laboratories spread across the country.

FPO

Indian agriculture is predominantly characterised by large number of dispersed and fragmented small holdings. Around 85% of the land holdings belong to small and marginal farmers. Being unorganised, these farmers are unable to realize good value for their produce.

Pilots implemented by SFAC, NABARD etc., indicate that the problems encountered by the small and marginal farmers can be mitigated to a large extent by organising them into Producer Organizations (POs). POs enable member-farmers to reap the benefits of economies of scale in purchase of inputs, processing and marketing of their produce. Forming a producer organization can also provide the member-farmers access to timely and adequate credit and provide linkages to markets.

*National Bank for Agriculture and Rural Development (NABARD)

What is a Producer Organisation (PO)?

- A Producer Organisation (PO) is a legal entity formed by primary producers, viz. farmers, milk producers, fishermen, weavers, rural artisans, craftsmen.
- A PO can be a producer company, a cooperative society or any other legal form which provides for sharing of profits/benefits among the members.
- In some forms like producer companies, institutions of primary producers can also become member of PO.
- The PO is an organization of the primary producers. If the produce in question is a nonfarm
- item (for example, handloom or handicraft), then the PO will be that of non-farmers.
- The objective of the PO is to ensure better income realization to its members (who are producers) through aggregation and, if feasible, value addition.

What is a “Farmers Producer Organisation” (FPO)?

- It is one type of PO where the members are farmers.
- Small Farmers’ Agribusiness Consortium (SFAC) is providing support for promotion of FPOs.
- PO is a generic name for an organization of producers of any produce, e.g., agricultural, non-farm products, artisan products, etc.

What are the essential features of a PO?

- It is formed by a group of producers for either farm or non-farm activities.
- It is a registered body and a legal entity.
- Producers are shareholders in the organization.
- It deals with business activities related to the primary produce/product.
- It works for the benefit of the member producers.
- A part of the profit is shared amongst the producers.
- Rest of the surplus is added to its owned funds for business expansion.

What are the different legal forms of PO?

Producer Organisation can be registered under any of the following legal provisions:

- a. Cooperative Societies Act/ Autonomous or Mutually Aided Cooperative Societies Act of the respective State
- b. Multi-State Cooperative Society Act, 2002
- c. Producer Company under Section 581(C) of Indian Companies Act, 1956, as amended in 2013
- d. Section 25 Company of Indian Companies Act, 1956, as amended as Section 8 in 2013
- e. Societies registered under Society Registration Act, 1860
- f. Public Trusts registered under Indian Trusts Act, 1882

General Characteristics of FPO

- It deals with the pre-production, production and post-production activities of agriculture, horticulture, apiculture, sericulture, permitted minor forest produce and animal husbandry and fisheries including cattle, buffalo, goat, sheep, pig and poultry , etc.
- It deals with multiple products and services that are required by farmers specifically small and marginal producers.
- As regards management and governance: model of an FPO, it shall be as per the Law under which it has been incorporated/ registered, however, it has to demonstrate that it serves its farmer-members in general and small and marginal farmers, women farmers and SC/ST far
- A farmer can be a member in more than one FPOs considering his produce and agribusiness opportunity, however, will get matching equity grant from government only once for member in any one FPO only. mers in particular to avail on priority benefits under this policy.
- Currently, around 7,000 FPOs across the country, including Farmer Producer Companies (FPCs), have been established under various government bodies like SFAC, state governments, and NABARD over the past 8-10 years.