FDA – Food and Drug Administration

Your Objectives:

At the end of the lesson, you will be able to state the basic role and importance of the FDA in relation to the pharmaceutical industry.

The Food and Drug Administration (FDA)'s principal mandate under the US Department of Health and Human Services is to protect public health of the USA. It administrates the safety and efficacy of medicinal products used in both human and veterinary medicine, as well as biological products and foods, not to mention the safety and efficacy of medical devices and **radiation-emitting devices**. Furthermore, imported above-mentioned goods to USA from abroad is subject to the FDA's supervision.

The scope of the FDA's regulatory authority is very broad. The FDA's responsibilities are in close ties with several other government agencies, such as the Department of Agriculture (USDA), the Drug Enforcement Administration (DEA), Customs and Border Protection (CBP), and the Consumer Product Safety Commission (CPSC).

The following is a list, albeit not an exhaustive list, of traditionally-recognized product categories that fall under the FDA's regulatory jurisdiction.

Foods include:

- dietary supplements
- bottled water
- food additives
- infant formulas
- (other food products)*

Drugs include:

- (brand-name + generic) prescription
- non-prescription, over-the-counter

Biologics include:

- vaccines for humans
- blood and blood component products
- cellular and gene therapy products
- tissue and tissue component products
- allergens

Medical devices include:

- simple items like tongue depressors and bedpans
- complex technologies such as heart pacemakers
- dental devices
- surgical implants and prosthetics

Radiation-emitting electronic products:

- microwave ovens
- x-ray equipment
- laser products
- ultrasonic therapy equipment
- mercury vapor lamps
- sunlamps
- etc.

Cosmetics include:

- colour additives found in makeup and other personal care products
- skin moisturizers and cleansers
- nail polish and perfume

Veterinary products, such as:

- livestock feeds
- pet foods
- veterinary drugs and devices

Tobacco-based products, including:

- cigarettes
- cigarette tobacco
- roll-your-own tobacco
- smokeless tobacco

***** Aside from the FDA, the US Department of Agriculture plays a lead role in the regulating of some food products, such as meat, poultry and egg.

The FDA also inspects pharmaceutical manufacturing facilities worldwide, including facilities that manufacture active ingredients along with the finished product. Inspections follow a standard approach and are conducted by highly-trained FDA staff. The FDA also relies upon reports of potentially defective drug products from both the public and from the industry itself. The FDA will often use such reports to identify sites for which further inspection or investigation is needed. The majority of companies under inspection are found to be adequately compliant with the Current Good Manufacturing Practice (CGMP) regulations.

The FDA is responsible for the approval and market surveillance of food, medicines and medical devices. As such, the authority is endowed with a police force and may pass laws within the limits specified in the Code of Federal Regulations (21 CFR)

Although the FDA has advantages of having centralization and common rules, there are several procedures stipulated under a 510(k) for Class II, or a PMA, or premarket approval, for Class III medical device that the EU regulates through a network of centralized and decentralized agencies throughout its member states.

The FDA is known and feared for its on-site inspections through the resulting deviation reports (i.e. Form 483) and warning letters, as it monitors the market more actively than European authorities, searching for unwarranted* products and medical devices.

The consequences of deviations are more serious. They range from publishing all the crimes to violent plant closures, from import bans to the withdrawal of all products on the market by US marshalls—needless to say, at the company's expense.

* They are those which may not be developed, manufactured and sold in accordance with the regulations.