

USFDA AND WHO GUIDELINES



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USFDA



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INTRODUCTION

- *The United States Food and Drug Administration (best known as the FDA) is an agency within the U.S. Public Health Service, which is a part of the Department of Health and Human Services.*
- *FDA ensures that the food we eat is safe and wholesome, that the cosmetics we use won't harm us, and that medicines, medical devices, and radiation emitting consumer products such as microwave ovens are safe and effective.*
- *FDA also oversees food and drugs for pet and farm animals. Authorized by Congress to enforce the Federal Food, Drug, and Cosmetic Act and several other public health laws, the agency monitors the manufacture, import ,transport ,storage ,and sale of \$1 trillion worth of goods annually.*



CONSTITUTION

- *USFDA has over 9000 employees, located in 167 U.S. cities. Among its staff, FDA has chemists, microbiologist, and other scientists, as well as investigators and inspectors who visit 16000 facilities a year as part of their oversight of the business that FDA regulates.*



MISSION

- *To promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.*
- *With respect to such products, protect the public health by ensuring that the food are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled, and public health and safety are protected from the electronic product radiation.*
- *Participates through appropriate process with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.*



ORGANISATION

- *Centre for Biologics Evaluation and Research (CBER)*
- *Centre for Devices and Radiological Health (CDRH)*
- *Centre for Drug Evaluation and Research (CDER)*
- *Centre for Food Safety and Applied Nutrition (CFSAN)*
- *Centre for veterinary Medicine (CVM)*
- *National Centre for Toxicological Research (NCTR)*
- *Office of Chief Council (OCC)*
- *Office of Commissioner (OC)*
- *Office of Regulatory Affairs (ORA)*

GOVERNANCE

Governance takes place through the World Health Assembly, which is the supreme decision-making body; and the Executive Board, which gives effect to the decisions and policies of the Health Assembly. The Organization is headed by the Director-General, who is appointed by the Health Assembly on the nomination of the Executive Board.

1) World Health Assembly

The World Health Assembly is the decision-making body of WHO. It is attended by delegations from all WHO Member States and focuses on a specific health agenda prepared by the Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed programme budget.

2) Executive Board

The Executive Board is composed of 34 technically qualified members elected for three-year terms.

3) Director-General

Dr Tedros Adhanom Ghebreyesus is the Director-General of WHO, elected by a vote of Member States at the World Health Assembly on 23 May 2017.



WHAT USFDA REGULATES?

- *Biologics*
- *Product and Manufacturing establishment Licensing*
- *Safety to nation's blood supply*
- *Research to establish product standards and develop improved testing's methods*
- *Cosmetics*
- *Labeling*
- *Drugs*
- *Product approvals*
- *OTC and prescription drug labeling*
- *Drug manufacturing standards*
- *Foods*
- *Safety of all food products (except meat and poultry)*



- *Radiation-Emitting Electronic Products*
- *Radiation safety performance standards for microwave ovens, television receivers, diagnostic x-rays equipment, cabinet x-ray system (such as baggage x-rays at airports), Laser products, ultrasonic therapy equipment, mercury vapour lamps*
- *Veterinary products*



WHAT USFDA DOES NOT REGULATE ?

- *Advertising*
- *Alcohol*
- *Consumer Products*
- *Drugs of Abuse*
- *Health Insurance*
- *Meat and Poultry*
- *Pesticides*
- *Restaurants and Grocery Stores*
- *Water*

WHO





INTRODUCTION

- WHO is the directing and coordinating authority for health within the United Nations system.
- It is responsible for providing leadership on global health matters, shaping the health research agenda, setting norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.
- In the 21st century, health is a shared responsibility, involving equitable access to essential care and collective defense against transnational threats.



HISTORY

- *When diplomats met to form the United Nations in 1945, one of the things they discussed was setting up a global health organization.*
- WHO began when their Constitution came into force on 7 April 1948 – a date now celebrated every year as World Health Day. They are now more than 7000 people from more than 150 countries working in 150 country offices, in 6 regional offices and at headquarters in Geneva.



RESOURCES AND PLANNING

- *The framework for the financial resources and expenditures of WHO is derived from the 11th General Programme of Work, which covers the period 2006-2015.*
- *From 2008, a medium-term strategic plan will form the framework for WHO's results-based management. The six-year plan — for 2008 to 2013 — will cover three biennial budget periods, starting with the biennium 2008-2009.*
- *The strategic plan and its first Programme Budget for 2008-2009 were adopted by the World Health Assembly in May 2007.*



ROLE IN PUBLIC HEALTH

- *Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;*
- *Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;*
- *Setting norms and standards and promoting and monitoring their implementation;*
- *Providing technical support, catalyzing change, and building sustainable institutional capacity; and*
- *Monitoring the health situation and assessing health trends.*
- *These core functions are set out in the 11th General Programme of Work, which provides the framework for organization-wide programme of work, budget, resources and results. Entitled "Engaging for health", it covers the 10-year period from 2006 to 2015.*



WHO AGENDA

- *Promoting development*
- *Fostering health security*
- *Strengthening health systems*
- *Harnessing research, information and evidence*
- *Enhancing partnerships*
- *Improving performance*



ITS PEOPLE AND OFFICES

- *More than 8000 people from more than 150 countries work for the Organization in 147 country offices, six regional offices and at the headquarters in Geneva, Switzerland.*
- *In addition to medical doctors, public health specialists, scientists and epidemiologists.*
- *WHO staff include people trained to manage administrative, financial, and information systems, as well as experts in the fields of health statistics, economics and emergency relief.*

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THANK YOU