AAA BUSINESS SUPPLIES & INTERIORS

What is the FDA?

The Food and Drug Administration (FDA or USFDA) is a federal agency of the U.S. Department of Health and Human Services, one of the U.S. federal executive departments.
The FDA is responsible for protecting and promoting public health through the control and supervision of a series of product categories.

What does the FDA regulate?

Foods, Drugs, Medical Devices, Electronic Products that give off radiation, Cosmetics, Veterinary Products, and Tobacco Products.
Drugs: prescription drugs (both brand-name and generic), non-prescription (over-the-counter) drugs.
Medical Devices: simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices and surgical implants and prosthetics.

HOW DOES THE FDA REGULATE?

HOW DOES THE FDA REGULATE COMPANIES?

- FDA doesn't approve companies (health care facilities, laboratories, or manufacturers).
- FDA does have authority to inspect regulated facilities to verify that they comply with applicable good manufacturing practice regulations.
- Owners and operators of domestic or foreign food, drug, and most device facilities must register their facilities with FDA, unless an exemption applies. Blood and tissue facilities also must register with the agency.

HOW DOES THE FDA REGULATE DRUGS?

- FDA does not develop or test products before approving them.
- Drugs must be proven safe and effective to FDA's satisfaction before companies can market them in interstate commerce. To get FDA approval, drug manufacturers must conduct lab, animal, and human clinical testing and submit their data to FDA.
- FDA will then review the data and may approve the drug if the agency determines that the benefits of the drug outweigh the risks for the intended use.

HOW DOES THE FDA REGULATE MEDICAL DEVICES?

- FDA classifies devices according to risk.
- The highest-risk devices (Class III), such as mechanical heart valves and implantable infusion pumps, generally require FDA approval of a premarket approval application before marketing. Manufacturers must demonstrate with sufficient, valid scientific evidence that there is a reasonable assurance that the devices are safe and effective for their intended uses.

MEDICAL DEVICES REGULATION CONTINUED

▪ Generally, FDA "clears" moderate-risk medical devices (Class II) (for example dialysis equipment and many types of catheters) for marketing once it has been demonstrated that the device is substantially equivalent to a legally marketed predicate device that does not require premarket approval.

▪ Devices that present a low risk of harm to the user (Class I) (for example non-powered breast pumps, elastic bandages, tongue depressors, and exam gloves) are subject to general controls only, and most are exempt from premarket notification requirements.

CLASS I - LOW RISK	CLASS II - MODERATE RISK	CLASS III - HIGH RISK
Examples: ▪ Adhesive Bandages ▪ Wheelchairs ▪ Tongue Depressors	**Examples:** ▪ Catheters ▪ Needles ▪ Contact Lenses	**Examples:** ▪ Pacemakers ▪ Coronary Stents ▪ Orthopedic Implants
GENERAL CONTROLS		
WITH AND WITHOUT EXEMPTIONS		
	SPECIAL CONTROLS	
		PRE-MARKET APPROVAL

CATEGORIZING COVID-19 PRODUCTS & PRODUCT RELATED REGULATIONS

Drugs – Hand sanitizer, Disinfecting Wipes
Medical device – Thermometer,
Medical device but not regulated by FDA – general purpose face mask, general purpose face shield

NOT ALL FACE MASKS ARE ALIKE

Face Mask: A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.

Face Shield: A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user's eyes and face.

Surgical Mask: A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.

Filtering Facepiece Respirator: A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

N95 Respirator: A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

NIOSH Approved N95 Respirator: An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

Surgical N95 Respirator: A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of micro-organisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A **surgical N95 respirator** is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.