

FDA PRIMER

WHAT DOES FDA DO?

FDA is responsible for

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health

WHAT DOES FDA REGULATE?

FDA regulates

- foods, except for most meat and poultry products, which are regulated by the USDA
- food additives
- infant formulas
- dietary supplements
- human drugs
- vaccines, blood products, and other biologics
- medical devices, from simple items like tongue depressors, to complex technologies such as heart pacemakers
- electronic products that give off radiation, such as microwave ovens and X-ray equipment
- cosmetics
- feed, drugs, and devices used in pets, farm animals, and other animals
- tobacco products

WHAT DOESN'T FDA REGULATE?

- advertising (except for prescription drugs, medical devices, and tobacco products)
- alcoholic beverages
- some consumer products, such as paint, child-resistant packages, baby toys, and household appliances (except for those that give off radiation)
- illegal drugs of abuse, such as heroin and marijuana
- meat and poultry (except for game meats, such as venison, ostrich, and snake)
- restaurants and grocery stores

FDA shares the responsibility for regulating these products with other government agencies:

- pesticides (FDA, the USDA, and EPA) and water (FDA regulates bottled water, while EPA develops national standards for drinking water from municipal water supplies)

HOW DO I KNOW IF MY PRODUCT IS REGULATED BY FDA?

The link below is a simplified flow chart intended to provide companies a start in contacting a relevant FDA office with questions. It should not be used to make a final decision about the regulatory status of a product. You should refer to the [Federal Food, Drug, and Cosmetic Act and other laws FDA enforces](#) as well as [Title 21 of the Code of Federal Regulations](#).

<http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm237623.htm>