

Regulations at a Glance

	Foods	Dietary Supplements	Drugs
Safety			
FDA has the authority to declare a product misbranded if its labeling is false or misleading; civil and criminal penalties apply.	✓	✓	✓
FDA establishes Good Manufacturing Practices and inspects manufacturing plants to ensure that provisions are followed.	✓	✓	✓
FDA has the authority to declare a product adulterated if it is unsafe (whether the problem involves old or new ingredients or some other factor such as a contaminant or poor manufacturing conditions); civil and criminal penalties apply.	✓	✓	✓
Manufacturers' self-affirmation that a substance is Generally Recognized as Safe (GRAS) is subject to FDA review.	✓	✓	
FDA notification is required on the safety of new ingredients; FDA has the authority to disapprove.		✓	
FDA prior approval of safety and efficacy is required.			✓
FDA prior approval of the safety of new food additives is required.	✓		
Labeling			
Mandatory format for labeling required by FDA.	✓	✓	✓
FDA approval of "nutrient content claims" required under the Nutrition Labeling and Education Act (NLEA) and the Dietary Supplement Health and Education Act (DSHEA).	✓	✓	
Claims			
FDA approval of "health claims" required under NLEA.	✓	✓	
FDA has the authority to review label statements about structure and function effects under DSHEA.	✓	✓	
Advertising			
FTC requires that advertising claims be truthful, not misleading and substantiated by scientific evidence.	✓	✓	✓