

TABLE 2: CAPACITY OF FDA'S LEGAL AUTHORITY TO ACHIEVE THE PRIMARY GOALS OF REGULATORY OVERSIGHT FOR NANOTECHNOLOGY PRODUCTS

	Cosmetic Ingredient	Whole Food	Dietary Supplement	GRAS Food Ingredient	Food Additive	Food Packaging	Medical Device	OTC Drug	New Drug
Pre-Market									
Obtain Early Information on Pipeline	None	None	None	Weak	Weak	Weak	Moderate	Weak	Moderate
Enforce Safety and Testing Requirements	Weak	None	Weak	Moderate	Strong	Strong	Strong	Strong	Strong
Place Burden To Prove Safety on Sponsor	Weak	None	Weak	Moderate	Strong	Strong	Strong	Strong	Strong
Review Safety Prior to Marketing	None	None	Weak	Weak	Strong	Strong	Strong	Moderate	Strong
Post-Market									
Require Needed Monitoring and Testing	Weak	None	None	None	Weak	None	Strong	Weak	Moderate
Require Timely Adverse Event Reporting	None	None	None	None	Weak	None	Strong	None	Strong
Inspect Facilities and Safety Records	Weak	Moderate	Moderate	Moderate	Moderate	Moderate	Strong	Strong	Strong
Remove Unsafe Products from Market	Moderate	Moderate	Moderate	Strong	Moderate	Strong	Strong	Strong	Strong