



FDA's Approach to Regulation of Nanotechnology Products

- Nanotechnology Guidance Documents (</science-research/nanotechnology/nanotechnology-guidance-documents>)
- Nanotechnology Fact Sheet (</science-research/nanotechnology/nanotechnology-fact-sheet>)

As a public health agency using scientific information to make regulatory decisions about products ranging from cosmetics to chemotherapy agents to food packaging, FDA has long encountered the combination of promise, risk, and uncertainty that accompanies emerging technologies. Nanotechnology is not unique in this regard. Materials can exhibit new or altered physicochemical properties at nanoscale dimensions, which can enable the development of novel products. The very changes in biological, chemical and other properties that can make nanotechnology applications so exciting, however, also may merit examination to determine any effects on product safety, effectiveness, or other attributes.

The application of nanotechnology may result in product attributes that differ from those of conventionally-manufactured products, and thus evaluations of safety or effectiveness of FDA-regulated products that include nanomaterials or otherwise involve the application of nanotechnology should consider the unique properties and behaviors that nanomaterials may exhibit. However, FDA does not categorically judge all products containing nanomaterials or otherwise involving the application of nanotechnology as intrinsically benign or harmful. FDA will regulate nanotechnology products under existing statutory authorities, in accordance with the specific legal standards applicable to each type of product under its jurisdiction.

Consistent with Executive Order 13563 (<http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order>) on improving regulation, as well as with the White House policy statements on regulating emerging technologies (<https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/for-agencies/Principles-for-Regulation-and-Oversight-of-Emerging-Technologies-new.pdf>) and applications of nanotechnology (<https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>), FDA supports innovation and the safe use of nanotechnology in FDA-regulated products under appropriate and balanced regulatory oversight. By enhancing its scientific expertise and tools necessary to assess the safety and, as applicable, effectiveness of products (see FDA's nanotechnology regulatory science research plan (</science-research/nanotechnology/2013-nanotechnology-regulatory-science-research-plan>)), FDA can enable the responsible development of products with new and beneficial properties. FDA intends to ensure transparent and predictable regulatory pathways grounded in the best available science. To that end, FDA's regulatory approach will have the following attributes:

- ***FDA is maintaining its product-focused, science-based regulatory policy.*** Technical assessments will be product-specific, taking into account the effects of nanomaterials in the particular biological and mechanical context of each product and its intended use. And the

particular policies for each product area, both substantive and procedural, will vary according to the statutory authorities. We advise manufacturers to consult with the FDA early in their development process to facilitate a mutual understanding of the scientific and regulatory issues for their nanotechnology products.

- ***FDA's approach respects variations in legal standards for different product classes.*** Food additives are considered safe when there is a reasonable certainty of no harm from their intended use[1]. Drugs, by contrast, are evaluated not only on the basis of their risk profile but also their predicted benefit.[2] These differing legal standards demonstrate how different contexts could lead to different regulatory outcomes, even if two products present the same level of risk. Other products regulated by FDA are subject to yet different standards for safety or effectiveness. The result may be divergent regulatory outcomes for different product classes and different applications of nanomaterials, even where objective measures of risk are similar.
- ***Where premarket review authority exists, attention to nanomaterials is being incorporated into standing procedures.*** For example, new drugs, new animal drugs, biologics, food additives,[3] color additives, certain human devices, and certain new dietary ingredients in dietary supplements are subject to premarket review requirements. Premarket review processes for these products require applicants to submit data to answer questions related to the safety, effectiveness (where applicable), or regulatory status of the product. Individual premarket review procedures include attention to whether the use of nanomaterials suggests the need for additional data on safety or effectiveness, as applicable[4].
- ***Where statutory authority does not provide for premarket review, consultation is encouraged to reduce the risk of unintended harm to human or animal health.*** Some FDA regulated products, such as dietary supplements (except certain new dietary ingredients), cosmetics (except color additives), and food (except food or color additives) are not subject to mandatory premarket review. In these cases, FDA relies on publicly available or voluntarily submitted information, adverse event reporting (where applicable), and on post-market surveillance activities, to provide oversight. Where nanotechnology applications are involved, FDA encourages manufacturers to consult with the agency before taking their products to market. Such consultation can help FDA to advise companies, review safety information, and design any necessary post-marketing safety oversight.
- ***FDA will continue post-market monitoring.*** FDA will continue to monitor the marketplace for products containing nanomaterials and will take actions, as needed, to protect consumers.
- ***Industry remains responsible for ensuring that its products meet all applicable legal requirements, including safety standards.*** Regardless of whether products are subject to premarket review or authorization, manufacturers are required to ensure that their product satisfies applicable safety standards and complies with other applicable requirements. Therefore, industry must work with current information in product development, and continue to monitor products once marketed. FDA encourages industry to consult early with the agency to address questions related to the regulatory status, or to the safety, effectiveness, or other attributes of products that contain nanomaterials or otherwise involve application of nanotechnology. These early consultations afford an opportunity to clarify the methodologies and data that will be needed to meet the sponsor's obligations. Additional public meetings or workshops may be held to advance regulatory science, identify product-specific data needs, or seek input on specific issues.

- ***FDA will collaborate, as appropriate, with domestic and international counterparts on regulatory policy issues.*** FDA engages in policy dialogue with other U.S. government agencies through the Emerging Technologies Interagency Policy Coordination Committee (<http://www.whitehouse.gov/blog/2010/05/15/emerging-technologies-ipc-has-inaugural-meeting>) and other forums, among other things, to contribute to overarching U.S. government policies relevant to nanotechnology and, as appropriate, coordinate its policy activities. FDA also works with foreign regulatory counterparts to share perspectives and information on the regulation of nanotechnology products and their intended uses.
- ***Both for products that are not subject to premarket review and those that are, FDA will offer technical advice and guidance, as needed, to help industry meet its regulatory and statutory obligations.*** FDA prepares guidance documents for its staff, applicants/sponsors, and the public to describe the agency's interpretation of or policy on a regulatory issue. Guidance documents will emerge over time, and (depending upon the product-class) will address interpretation of relevant statutory and regulatory standards, and provide guidance on the technical data needed to meet those standards (see list below for guidances already published). FDA will tailor guidances to the unique confluence of the statute governing the product-class, the level of scientific knowledge relevant to those applications, and the likely extent of effects on human and animal health.

For additional information or specific questions related to FDA's nanotechnology regulatory policies, contact:

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[1] See Federal Food Drug and Cosmetic Act (FFDCA) sections 409 (21 U.S.C. 348) and 21 CFR 170.3(i).

[2] See FD&C Act § 505 (21 U.S.C. 355); and 21 CFR 330.10(a)(4)(iii).

[3] Includes food contact substances, such as food packaging.

[4] Premarket review may also address issues other than safety or effectiveness, *e.g.* product identity verification and manufacturing controls.