II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information has been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: December 12, 2017.

Leslie Kux,
Associate Commissioner for Policy.
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“Drug Products, Including Biological Products, That Contain Nanomaterials.” This guidance applies to human drug products, including those that are biological products, in which a nanomaterial is present in the finished dosage form. This draft guidance discusses both general principles and specific considerations for the development of drug products containing nanomaterials, including considerations for establishing the equivalence of such products with other drugs. Considerations for quality, nonclinical, and clinical studies are discussed as they relate to drug products containing nanomaterials throughout product development and production.

This draft guidance does not limit or classify the types of nanomaterials that can be used in drug products. Rather, it is focused on the deliberate and purposeful manipulation and control of dimensions to produce specific physicochemical properties which may warrant further evaluation with regards to safety, effectiveness, performance, and quality. This guidance does not address, or presuppose, what ultimate regulatory outcome, if any, will result for a particular drug product that contains nanomaterials. Issues such as the safety, effectiveness, public health impact, or the regulatory status of drug products that contains nanomaterials are currently addressed on a case-by-case basis using FDA’s existing review processes. Current CDER and CBER guidance documents and requirements for the evaluation and maintenance of quality, safety, and efficacy, apply to drug product containing nanomaterials that otherwise fall within their scopes. In addition, the Agency may continue to develop guidance addressing certain specific commonly-used types of nanomaterials, e.g., some liposomes, to better address the challenges in evaluating and characterizing the quality and performance of drug products that incorporate them.

This draft guidance is one of several FDA guidance documents related to FDA-regulated products that may involve the use of nanotechnology. FDA has not established regulatory definitions of “nanotechnology,” “nanomaterial,” “nanoscale,” or other related terms. In Guidance for Industry, “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology,” issued in 2014, FDA described certain considerations for determining whether FDA-regulated products involve the application of nanotechnology. FDA will apply these considerations broadly to all FDA-regulated products, including drug products within the scope of this draft guidance. The use of the term “nanomaterial” in this draft guidance, as in other FDA guidance documents, does not constitute the establishment of a regulatory definition. Rather, we use this term for ease of reference only. See section II of the draft guidance for additional information.

FDA requests comment on the draft guidance. We also seek comment on the terminology, including the term “nanomaterial”, as used in the draft guidance.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on Drug Products, Including Biological Products, That Contain Nanomaterials. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This draft guidance includes recommendations related to collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). The collections of information that are related to the burden of submitting investigational new drug applications are covered under 21 CFR part 312 and have been approved under OMB control number 0910–0014. The collections of information related to the burden of submitting new drug applications, including supplemental applications, are covered under 21 CFR part 314 and have been approved under OMB control number 0910–0001. The collections of information related to the burden of submitting section 351(k) biosimilar applications have been approved under OMB control number 0910–0719. The collections of information related to the burden of complying with the current good manufacturing process recordkeeping requirements under 21 CFR part 211 have been approved under OMB control number 0910–0139. The collections of information related to the burden of complying with the environmental impact requirements under 21 CFR part 25 have been approved under OMB control number 0910–0322. The design and testing of prescription drug labeling required under 21 CFR 201.56 and 201.57 is approved under OMB control number...
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