(GDUFA I), beginning October 1, 2012, FDA agreed to act on received ANDAs within established time frames. As part of this undertaking, the Agency instituted the use of multiple forms of communicating with an applicant regarding the review of an application, including issuance of Complete Response Letters (CRLs) and IRs.[1]

Under GDUFA I, FDA issued a CRL after completing a review of an ANDA. The CRL described all the deficiencies identified in the ANDA that must be satisfactorily addressed before the ANDA can be approved. Issuance of a CRL also completed the ANDA's review cycle, with the next review cycle beginning when the applicant amended the ANDA by submitting a complete response to all deficiencies listed in the CRL.

FDA used IRs to ask for information that would assist reviewers during the course of the review or to convey deficiencies identified in the application in advance of a CRL. IRs did not stop the review clock, did not signal the completion of a review cycle, and were not always used consistently across divisions or offices.

In negotiations held as part of the Generic Drug User Fee Amendments of 2017 (GDUFA II), it was agreed that FDA will: (1) Issue an IR to request further information or clarification that is needed or would be helpful to allow completion of a discipline review and/or (2) issue a new type of letter for ANDAs, known as a DRL, to convey preliminary thoughts on possible deficiencies found by a discipline reviewer and/or review team for its or their portion of the application under review at the conclusion of a discipline review.[2]

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Information Requests and Discipline Review Letters Under GDUFA.'' 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.

[1] Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Public Law 112–144 (2012). FDASIA includes GDUFA I, and by reference, the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I Commitment Letter).

[2] FDA Reauthorization Act of 2017 (FDARA), Public Law 115–52 (2017). FDARA includes GDUFA II, and by reference, the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018–2022 (GDUFA II Commitment Letter).

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.

[FR Doc. 2017–27124 Filed 12–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–0759]

Drug Products, Including Biological Products, That Contain Nanomaterials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Drug Products, Including Biological Products, that Contain Nanomaterials.'' This draft guidance has been developed to provide industry with the Agency's current thinking for the development of human drug products, including those that are biological products, that contain nanomaterials. The draft guidance also includes recommendations for applicants and sponsors of investigational, premarket, and postmarket submissions for these products.

DATES: Submit either electronic or written comments on the draft guidance by March 19, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–0759 for ''Drug Products, Including Biological Products, that Contain Nanomaterials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Katherine Tyner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4146, Silver Spring, MD 20993–0002, 301–796–0085; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''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

0910–0572. Concerning the immediate container label and outer container or package, in the **Federal Register** of December 18, 2014 (79 FR 75506), we published a proposed rule on the electronic distribution of prescribing information for human prescription drugs, including biological products. In Section VII, Paperwork Reduction Act of 1995, we estimated the burden to design (including revisions), test, and produce the label for a drug's immediate container and outer container or package, as set forth in 21 CFR part 201 and other sections in subpart A and subpart B.

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, https;www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: December 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27133 Filed 12–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6617]

Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' The purpose of this guidance is to describe the FDA's current recommendations on how to group patients with different molecular alterations for eligibility in clinical trials; and general approaches to evaluating the benefits and risks of targeted therapeutics within a clinically defined disease where some molecular alterations may occur at low frequencies.

DATES: Submit either electronic or written comments on the draft guidance by February 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–6617 for ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.