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Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,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Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.''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DATES: Submit either electronic or written comments on the draft guidance by February 16, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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.

FOR FURTHER INFORMATION CONTACT: Michael Pacanowski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 301–796–3919; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' This guidance is intended to assist sponsors in designing drug development programs to generate the evidence needed to demonstrate efficacy of a targeted therapy across subsets of patients with different underlying molecular alterations within a disease, where some molecular alterations may occur at low frequencies.

In recent years, advances in our understanding of the molecular pathology of many diseases have led to the development of targeted therapies. Although variability in drug response has long been recognized in drug development, targeted therapies present new challenges in addressing the heterogeneity in drug response because the pharmacological effect of a targeted therapy is often related to a particular molecular alteration (*e.g.,* a mutation, gene fusion, epigenetic change, etc.). Many clinically defined diseases are caused by a range of different molecular alterations, some of which may occur at low frequencies, that impact a common protein or pathway involved in the disease pathogenesis. In a population of patients with the same clinical disease, the heterogeneity in the molecular etiology may result in different responses to a particular therapy. However, certain targeted therapies may be effective in multiple groups of patients that have different underlying molecular alterations. Therefore, FDA is providing guidance on the type and quantity of evidence that can demonstrate efficacy across molecular subsets within a disease.

This guidance addresses the following important topics in evaluating the benefits and risks of targeted therapeutics within a disease where some molecular alterations may occur at low frequencies:

- Identification of patients for inclusion in clinical trials
- Interpretation of study results and generalizability of findings
- Benefit-risk determination and therapeutic product labeling
- Refining the indicated population after the initial approval

In addition to comments on the general content of the draft guidance, FDA requests input on whether the principles described for grouping molecular subsets for clinical trial enrollment should be limited to diseases with low-frequency molecular alterations or whether they could be broadly applicable to all targeted therapies.

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 ''Developing Targeted Therapies in Low-Frequency Molecular Subsets of a Disease.'' 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. 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/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: December 12, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–27156 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–N–6356]

Investigational In Vitro Diagnostics Used in Clinical Investigations of Therapeutic Products; Draft Guidance for Industry, Food and Drug Administration Staff, Sponsors, and Institutional Review Boards; 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 the draft guidance entitled ''Investigational IVDs Used in Clinical Investigations of Therapeutic Products.'' This draft guidance is intended to assist sponsors of clinical investigations of therapeutic products that also include investigational in vitro diagnostics (IVDs) and institutional review boards (IRBs) that review such investigations in complying with the Investigational Device Exemption (IDE) regulation. This draft guidance is also intended to assist FDA staff participating in the review of these investigations. This draft guidance is not final nor is it in effect at this time.

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.''