Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3380]

Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' This draft guidance describes considerations for the development and labeling of *in vitro* companion diagnostic devices (referred to as *companion diagnostics* in this document) to support the indicated uses of multiple drug or biologic oncology products (referred to as *therapeutic products* or *oncology therapeutic products* in this document), when appropriate. The draft guidance includes factors for considering when broader labeling (*i.e.,* labeling that is expanded) of a companion diagnostic would be appropriate. Oncology companion diagnostics with broader evidence-based indications will optimally facilitate clinical use.

DATES: Submit either electronic or written comments on the draft guidance by February 5, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2018–D–3380 for ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' 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 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; the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002; or 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. The draft guidance may also be obtained by mail by calling FDA's Center for Biologics Evaluation and Research (CBER) at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: 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; Reena Philip, Center for

Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5680, Silver Spring, MD 20993–0002, 301–796–6179; or Julie Schneider, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2208, Silver Spring, MD 20993–0002, 240–402–4658.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Developing and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' This draft guidance describes considerations for the development and labeling of companion diagnostics to support the indicated uses of multiple therapeutic oncology products, when appropriate. This draft guidance expands on existing policy, surrounding broader labeling, which notes that in some cases, if evidence is sufficient to conclude that the companion diagnostic is appropriate for use with a specific group or class of therapeutic products (as discussed in the draft guidance), the companion diagnostic's intended use/indications for use should name the specific group or class of therapeutic products, rather than specific products. To describe FDA's thinking on the topic, the draft guidance discusses a specific example of companion diagnostics for a specific biomarker, disease, and specimen type (specific epidermal growth factor receptor mutations in tumors of patients with nonsmall cell lung cancer in tissue specimens).

Trials designed to support approval of a specific therapeutic product and a specific companion diagnostic have led to companion diagnostic labels that reference only a specific therapeutic product(s). Such specificity in labeling can limit a potentially broader use of a companion diagnostic that may be scientifically appropriate. In clinical practice, an oncologist generally considers the mutation profile of the tumor along with other factors when determining the treatment for a patient, such as the toxicity profile of the therapeutic product, the patient's preference, and formulary options. When a companion diagnostic is labeled for use with a specific therapeutic product, the clinician may need to order a different companion diagnostic (*i.e.,* one that includes other therapeutic products in the labeling), obtain an additional biopsy(ies) from a patient, or both, to have additional therapy treatment options.

The draft guidance describes considerations for when broader labeling may be scientifically appropriate and when it may not. FDA recommends developers of therapeutic oncology products and associated companion diagnostics collaboratively consider development programs that may result in broader labeling of companion diagnostics that are most clinically useful. Developers are encouraged to discuss development programs that could result in broader labeling with the CBER, Center for Devices and Radiological Health (CDRH), or Center for Drug Evaluation and Research, in coordination with the Oncology Center of Excellence, as appropriate, early to determine if the approach described in this guidance is appropriate for consideration. Developers whose approved companion diagnostics may be appropriate for broader labeling are encouraged to contact CDRH or CBER, as appropriate, to discuss.

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 and Labeling *In vitro* Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products.'' 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. Other Issues for Consideration

In addition to providing stakeholders an opportunity to comment on the draft guidance, the Agency is interested in responses from stakeholders to the following:

1. Please describe any specific challenges with developing the evidence needed to identify in labeling a companion diagnostic for use with a specific group or class of oncology therapeutic products, rather than a specific therapeutic product. For example, please describe any challenges resulting from industry or business practices, including business agreements. What actions can FDA take to address the challenge(s)?

2. Please describe any specific challenges with submitting a premarket approval (PMA) supplement to FDA to expand the labeling for an approved companion diagnostic for use with a specific group or class of oncology therapeutic products. What actions can FDA take to address the challenge(s)?

3. Please describe any additional actions FDA can take to facilitate or encourage broader, evidence-based labeling that supports the use of a specific group or class of oncology therapeutic products with a companion diagnostic.

4. The guidance notes that variations in defined cut-points established for specific biomarkers for companion diagnostics can lead to challenges in implementing broader labeling for a specific group or class of oncology therapeutic products. Are there actions that FDA, or the broader scientific community, can take to facilitate standardization in this area?

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A through E, have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756; and the collections of information in the guidance ''De Novo Classification Process (Evaluation of Automatic Class III Designation)'' have been approved under OMB control number 0910–0844.

IV. 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 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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