declaration of a public health emergency related to COVID–19 and mobilized the Operating Divisions of HHS.[1] In addition, on March 13, 2020, the President declared a national emergency in response to COVID–19.[2] Due to the need to act quickly and efficiently to respond to the COVID–19 public health emergency, the guidance entitled ''Guidance on Chloroquine Phosphate'' is being issued as a final guidance and not as a draft guidance as is usual under the guidance for industry entitled ''Bioequivalence Recommendations for Specific Products.''

II. Drug Products for Which New Final Product-Specific Guidances are Available

FDA is announcing the availability of new final product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—FINAL PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Chloroquine phosphate Hydroxychloroquine sulfate

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These final guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These final guidances, represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the internet may obtain the guidances at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

[1] Secretary of Health and Human Services Alex M. Azar II, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), *available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*).

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (Mar. 13, 2020), *available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

The guidances also are available at FDA's web page titled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (*https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and through FDA's web page titled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: April 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07751 Filed 4–13–20; 8:45 am]

BILLING CODE 4164–01–P

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 of Oncology Therapeutic Products; 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 final guidance for industry entitled ''Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products'' and encourages the submission of premarket approval application (PMA) supplements containing the needed information to modify the intended use of specific companion diagnostics as described in this notice (*i.e.,* companion diagnostics that identify patients with nonsmall cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication). This 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 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 indications will optimally facilitate clinical use. The guidance announced in this notice finalizes the draft guidance entitled ''Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products'' dated December 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on April 14, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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 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 this guidance to the Office Policy, 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; 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 guidance document.

Submit PMA supplements to the Center for Devices and Radiological Health Document Control Center, 10903 New Hampshire Ave., Bldg. 66, Rm. G609, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Reena Philip, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3316, Silver Spring, MD 20993–0002, 301–796–6179; 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; 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 final guidance for industry entitled ''Developing and Labeling In vitro Companion Diagnostic Devices for a Specific Group of Oncology Therapeutic Products.'' This guidance describes considerations for the development and labeling of companion diagnostics to support the indicated uses of multiple therapeutic oncology products, when appropriate. This guidance builds upon existing policy regarding labeling of companion diagnostics. In a prior guidance entitled ''In Vitro Companion Diagnostic Devices'' (August 2014), the Agency stated that if evidence is sufficient to conclude that the companion diagnostic is appropriate for use with a specific group of therapeutic products (as discussed in the guidance), the companion diagnostic's intended use/indications for use should name the specific group, rather than specific products. This guidance expands on the policy statement in the 2014 guidance by recommending that companion diagnostic developers consider a number of factors, including but not limited to those discussed in this guidance, when determining whether their test could be developed, or the labeling for approved companion diagnostics could be revised through a supplement, to support a broader labeling claim such as use with a specific group of oncology therapeutic products (rather than listing an individual therapeutic product(s)). To describe FDA's thinking on the topic, the 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 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 Center for Biologics Evaluation and Research (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. Developers of the companion diagnostics discussed in the guidance as an example should see the ''Other Issues for Consideration'' section of this notice for information regarding broader labeling for those companion diagnostics.

This guidance finalizes the draft guidance entitled ''Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group or Class of Oncology Therapeutic Products'' dated December 2018 (83 FR 63166). Comments received on the draft guidance were taken into consideration when finalizing the guidance. Based on the comments received, clarifications were made and information regarding the content of broader labeling was added.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Developing and Labeling In Vitro Companion Diagnostic Devices for a Specific Group 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.

II. Other Issues for Consideration

Based on publicly available information, which includes valid scientific evidence (*i.e.,* clinical and scientific experience) with specific companion diagnostics and the associated therapeutic products, FDA has concluded that certain statements set forth in the FDA-approved labels of these companion diagnostics, related to intended use with therapeutic products, can be modified. The specific companion diagnostics are those discussed as an example in the guidance announced in this notice (*i.e.,* companion diagnostics that identify patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication). FDA believes it is appropriate for sponsors to consider modifying the intended use of these companion diagnostics to describe the specific group of oncology therapeutic products, rather than listing individual therapeutic product(s). The guidance states that, rather than listing individual therapeutic product(s), the intended use for the indication for the specific companion diagnostics would be, ''identifying patients with NSCLC whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and are suitable for treatment with a tyrosine kinase inhibitor approved by FDA for that indication.'' It is possible for the companion diagnostics to also have other indications, not captured by the broader indication. FDA encourages the submission of PMA supplements, identifying the change and referring to this notice as the reason for the change, to request modification of the intended use of these companion diagnostics. This broader labeling may enable greater flexibility for clinicians in choosing the most appropriate therapeutic product based on a patient's biomarker status.

In the **Federal Register** document that announced the availability of the draft guidance, FDA requested feedback on specific issues, including challenges with developing the evidence needed to support broader companion diagnostic labeling, challenges with submitting a PMA supplement to broaden the labeling of an approved companion diagnostic and actions FDA can take to facilitate or encourage broader companion diagnostic labeling in oncology. Comments that stakeholders submitted to the docket for the draft guidance are generally supportive of the concept of broader labeling for companion diagnostics in oncology to facilitate the treatment of patients with cancer. To encourage implementation of broader labeling of companion diagnostics in oncology, FDA is finalizing the guidance and encouraging submission of PMA supplements containing the needed information for FDA review of the modified labeling of the companion diagnostics discussed in the guidance as an example.

III. Paperwork Reduction Act of 1995

This 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. 3501–3521). 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 and Meetings for Medical Device Submissions: The Q-Submission Program'' 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 guidance at either *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics,* or *https://www.regulations.gov.*

Dated: April 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07816 Filed 4–13–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Early Career Reviewer Program Online Application and Vetting System (Center for Scientific Review)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular