initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based, harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries. FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency, International Federation for Animal Health—Europe; FDA; the U.S. Department of Agriculture; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry, and Fisheries; and the Japanese Veterinary Products Association. Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry in Canada, one representative from the government of South Africa, and one representative from the industry in South Africa. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

II. Guidance for Industry on Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV

In the **Federal Register** of December 28, 2018 (83 FR 67289), FDA published the notice of availability for a draft guidance entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV'' (VICH GL58), giving interested persons until February 26, 2019, to comment on the draft guidance. FDA did not receive comments on the draft guidance. Comments received by other VICH member regulatory agencies were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated December 2018.

The VICH Steering Committee held a meeting in September 2019 and agreed that the final guidance document entitled ''Stability Testing of New Veterinary Drug Substances and Medicinal Products in Climatic Zones III and IV'' (VICH GL58) should be made available for implementation. This guidance document is an annex to the VICH parent stability guidance, GFI #73 (VICH GL3(R)), ''Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision),'' [1] and provides guidance regarding the stability data package for a new veterinary drug substance and medicinal product to be included in a registration or application submitted within the regions in climatic zones III and IV. This guidance provides additional guidance on the storage conditions for stability testing in countries located in Climatic Zones III (hot and dry) and IVB (hot and very humid), which are not covered by GFI #73 (VICH GL3(R)). This guidance document seeks to exemplify the core stability data package for new veterinary drug substances and medicinal products, but leaves flexibility to encompass the variety of different practical situations that may be encountered due to specific scientific considerations and characteristics of the materials being evaluated.

III. Significance of Guidance

This guidance, developed under the VICH process, is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents do not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The guidance represents the current thinking of FDA on this topic. 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] *https://www.fda.gov/media/70241/download.*

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. 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 part 514 have been approved under OMB control number 0910–0032.

V. Electronic Access

Persons with access to the internet may obtain the final guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry* or *https://www.regulations.gov.*

Dated: April 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07752 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–2007–D–0369]

Product-Specific Guidances; 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 final guidances for industry entitled ''Guidance on Chloroquine Phosphate'' and ''Guidance on Hydroxychloroquine Sulfate.'' These guidances provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website. The guidance entitled ''Guidance on Hydroxychloroquine Sulfate'' was developed using the process described in that guidance and finalizes the draft guidance of the same title issued in April 2011. The guidance entitled ''Guidance on Chloroquine Phosphate'' is being implemented without prior public comment because FDA has determined that prior participation for

this guidance is not feasible or appropriate in light of the Coronavirus Disease 2019 (COVID–19) public health emergency but remains subject to comment in accordance with the Agency's good guidance practices.

DATES: Submit either electronic or written comments on Agency guidances at any time.

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–2007–D–0369 for ''Product-Specific Guidances; Guidance for Industry; Availability.'' 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.govinfo.gov/content/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 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 guidance documents.

FOR FURTHER INFORMATION CONTACT: Mara Miller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4709C, Silver Spring, MD 20993–0002, 301–796–0683.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*.

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. Under that process, draft guidances are posted on FDA's website and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final guidances or publishes revised draft guidances for comment. Guidances were last announced in the **Federal Register** on March 3, 2020. This notice announces final product-specific guidances that are posted on FDA's website.

The guidance entitled ''Guidance on Hydroxychloroquine Sulfate'' was developed using the process described in that guidance and finalizes the draft guidance of the same title issued in April 2011.

The guidance entitled ''Guidance on Chloroquine Phosphate'' is being implemented without prior public comment because FDA has determined that prior participation for this guidance is not feasible or appropriate (see 21 CFR 10.115(g)(2)). This document is being implemented immediately but remains subject to comment in accordance with the Agency's good guidance practices, and FDA intends to revise the guidance as warranted and appropriate after reviewing any public comment we receive.

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19). On January 31, 2020, the Department of Health and Human Services (HHS) issued a

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.''