



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“Guidance on Hydroxychloroquine Sulfate” was developed using the process described in that guidance and finalizes the draft guidance of the same title issued in April 2011.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

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/>.

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>.

The guidances also are available at FDA's webpage 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 webpage 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.

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