21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-Submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and Food and Drug Administration Staff.	CLIA Waiver Applications	0910–0598
Administrative Procedures for CLIA Categorization—Guidance for Industry and Food and Drug Administration Staff.	Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization (42 CFR 493.17).	0910–0607

Dated: September 23, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21463 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1548]

Failure To Respond to an Abbreviated New Drug Application Complete Response Letter Within the Regulatory Timeframe; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' This guidance is intended to assist applicants in responding to complete response letters (CRLs) to abbreviated new drug applications (ANDAs) submitted to FDA under the Federal Food, Drug, and Cosmetic Act. This guidance provides information and recommendations regarding potential courses of action for an ANDA applicant after issuance of a CRL as well as the actions that FDA may take if the applicant fails to respond to a CRL. In addition, this guidance recommends information an applicant may submit in its request for an extension to respond to a CRL as well as a non-exhaustive list of factors that FDA will consider in determining whether such a request is reasonable.

DATES: Submit either electronic or written comments on the draft guidance by November 30, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2020–D–1548 for ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' 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, 240–402–7500.

- 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, 240–402–7500.

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 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: Lisa Bercu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–6902, 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 ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' This guidance provides information and recommendations regarding the potential courses of action for an ANDA applicant after issuance of a CRL as well as the actions that FDA may take if the applicant fails to respond to the CRL. This guidance also identifies information that an applicant may submit in its request for an extension to respond to a CRL as well as a non-exhaustive list of factors that FDA will consider in determining whether such a request is reasonable.

As defined in 21 CFR 314.3(b), a CRL is a written communication to an applicant from FDA usually describing all of the deficiencies that the Agency has identified in an NDA or ANDA that must be satisfactorily addressed before it can be approved. After receiving a CRL, an applicant must, under § 314.110(b) (21 CFR 314.110(b)): (1) Resubmit the ANDA (*i.e.,* submit all materials needed to fully address all deficiencies identified in the CRL), (2) withdraw the application, or (3) request the opportunity for a hearing. If an applicant fails to take one of these three actions within 1 year after issuance of a CRL, FDA may consider this failure to be a request to withdraw the ANDA unless the applicant has requested an extension of time in which to address all deficiencies identified in the CRL.

Historically, FDA, in its discretion, has liberally granted requests for multiple extensions to respond to an individual CRL. However, FDA has seen a steady increase of applications pending with industry for more than a year. Lengthy response times because of multiple extensions, which can result in a submission addressing deficiencies years after the initial assessment of the ANDA and issuance of the CRL, are disruptive to the assessment process and can create additional assessment cycles. Over time, information submitted in the original ANDA can become obsolete because of changes such as new or revised United States Pharmacopeia requirements, reference listed drug labeling changes, or other events such as a facility evaluation becoming outdated. In addition, over time, there may have been changes in FDA assessors, and it may take time for them to familiarize themselves with the original submission. For these reasons, assessing an amendment submitted years after the initial ANDA assessment and issuance of the CRL diverts the Agency's limited resources from the review of other applications.

FDA is issuing this guidance as part of the ''Drug Competition Action Plan,'' which aims to increase competition in the market for prescription drugs, facilitate entry of high-quality and affordable generic drugs, and improve the public health. FDA intends for this guidance to promote efforts to address deficiencies more quickly, make the process for submitting and reviewing extension requests more efficient and predictable, and allow the Agency to focus its resources on ANDA assessment.

In addition to general comments on this guidance, FDA is interested in responses to the following questions:

1. Are there any categories of deficiencies in which a year would not be expected to be a sufficient amount of time to respond to a CRL?

2. Why may it take an applicant more than 1 year to respond to a CRL?

a. Does the patent landscape impact the timing of an applicant's response to a CRL?

b. Are there disincentives (*e.g.,* business reasons) to responding to a CRL within 1 year?

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 ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe.'' 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. Paperwork Reduction Act of 1995

This draft guidance for industry entitled, ''Failure to Respond to an ANDA Complete Response Letter Within the Regulatory Timeframe,'' describes information collection provisions that 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). In particular, the draft guidance refers to collection of information under § 314.110, Complete Response Letter to the Applicant, after FDA review of an ANDA and issuance of a CRL identifying deficiencies in the application to the ANDA applicant.

Any burden of communications, as outlined in 21 CFR 314.102 and 314.110, incurred during the review of new drug applications, ANDAs, and drug master files, is already accounted for as part of the FDA review process and attributable to other specific references in 21 CFR 314, within the OMB approved collection 0910–0001.

The draft guidance also refers to previously approved collections of information found in FDA regulations and approved under OMB control numbers 0910–0001 and 0910–0191. When finalized, the guidance will be included in 0910–0001.

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/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: September 18, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21469 Filed 9–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1824]

Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment; 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 ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' Sponsors may encounter challenges in identifying methods to assess the numerous and heterogeneous Coronavirus Disease 2019 (COVID–19)-related symptoms across subjects when designing clinical trials of drugs to treat or prevent COVID–19 in adult and adolescent outpatient subjects. To assist sponsors, this guidance describes an example with a set of common COVID–19-related symptoms as well as an approach to their measurement for use in clinical trials. Given the public health emergency presented by COVID–19, this guidance document is being implemented without prior public comment because FDA has determined that prior public participation is not feasible or appropriate, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 29, 2020. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

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–2020–D–1824 for ''Assessing COVID–19-Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID–19 Prevention or Treatment.'' 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, 240–402–7500.

- 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, 240–402–7500.

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 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 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. 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.

FOR FURTHER INFORMATION CONTACT: Elektra Papadopoulos, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6445, Silver Spring, MD 20993–0002, 301–796–0967; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903