sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

Section 1886(d)(5)(K)(viii) of the Act requires that as part of the process for evaluating new medical services and technology applications, the Secretary shall do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and presentations provided during this meeting will assist us as we evaluate the new medical services and technology applications for FY 2022. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2022 IPPS/LTCH PPS proposed rule.

II. Town Hall Meeting Format and Conference Call/Live Streaming Information

A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criterion for the FY 2022 new medical services and technology add-on payment applications. Information regarding the applications can be found on our website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Individuals who would like to present must register and submit their agenda item(s) via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

Depending on the number of applications received, we will determine if a second meeting day is necessary. A preliminary agenda will be posted on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* by November 23, 2020 to inform the public of the number of days of the meeting.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the FY 2022 IPPS/LTCH PPS proposed rule, the comments must be received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

B. Conference Call, Live Streaming, and Webinar Information

As noted previously, the Town Hall meeting will be held virtually due to the COVID–19 pandemic. There will be an option to participate in the Town Hall Meeting via live streaming technology or webinar and a toll-free teleconference phone line. Information on the option to participate via live streaming technology or webinar and a teleconference dial-in will be provided through an upcoming listserv notice and will appear on the final meeting agenda, which will be posted on the New Technology website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the website for updates.

C. Disclaimer

We cannot guarantee reliability for live streaming technology or a webinar.

III. Registration Instructions

The Division of New Technology in CMS is coordinating the meeting registration for the Town Hall Meeting on substantial clinical improvement. While there is no registration fee, individuals planning to present at the Town Hall Meeting must register to present.

Registration for presenters may be completed by sending an email to *newtech@cms.hhs.gov.* Please include your name, address, telephone number, email address and fax number.

Registration for attendees not presenting at the meeting is not required.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: October 8, 2020.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2020–22894 Filed 10–14–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1876]

Testing for Biotin Interference in In Vitro Diagnostic Devices; 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 entitled ''Testing for Biotin Interference in In Vitro Diagnostic Devices; Guidance for Industry.'' The guidance provides FDA's recommendations on the testing for interference by biotin on the performance of in vitro diagnostic devices (IVDs). The guidance is intended to help device developers and clinicians understand how FDA recommends biotin interference testing be performed, and how the results of the testing should be communicated to end users, including clinical laboratories and clinicians. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on October 16, 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–2019–D–1876 for ''Testing for Biotin Interference in In Vitro Diagnostic Devices; Guidance for Industry.'' 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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002 or the Office of 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. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Shruti Modi, 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 document entitled ''Testing for Biotin Interference in In Vitro Diagnostic Devices; Guidance for Industry.'' The guidance provides FDA's recommendations on the testing for interference by biotin on the performance of IVDs. The guidance is intended to help device developers and clinicians understand how FDA recommends biotin interference testing be performed, and how the results of the testing should be communicated to end users, including clinical laboratories and clinicians. The recommendations apply to IVDs, including devices that are licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) and used in donor screening, that use biotin technology.

Biotin, also known as vitamin B7, is a water-soluble vitamin often found in multivitamins, prenatal vitamins, and dietary supplements marketed for hair, skin, and nail growth. FDA has become aware of potential biotin interference with IVDs that use biotin/avidin interactions as part of the device technology. Biotin levels in samples from patients who consume more than the recommended daily intake of biotin can cause falsely high or falsely low results, depending on the test principle.

In the **Federal Register** of June 10, 2019 (84 FR 27781), FDA announced the availability of the draft guidance of the same title. FDA received a few

comments on the draft guidance and those comments were considered as the guidance was finalized. We considered comments on the recommended level of biotin concentration for evaluation. We decline to recommend evaluating a concentration level below 3,500 nanograms per milliliter. We believe this level is appropriate for minimizing the risk to patients from incorrect test results. Further, this level is consistent with best practices among the industry to test at three times the highest concentration levels observed, as recommended in the FDA-recognized standard published by the Clinical Laboratory Standards Institute. Other comments recommended FDA clarify or expand upon the necessity of mitigation strategies to address biotin interference other than labeling. We decline to recommend other specific mitigation strategies, but note that other mitigation strategies such as customer information letters and technical mitigations may be considered when the risk of potentially incorrect results from biotin interference could significantly affect patient or public health. Finally, we considered comments regarding additional types of information to be communicated to end-users, but we declined to provide more specific recommendations because manufacturers may not have sufficient data to provide more specific information in the labeling. In addition, editorial edits were made to improve clarity. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2019.

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 testing for biotin interference in in vitro diagnostic devices. 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 809 have been approved under OMB control number 0910–0485.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products,* or *https://www.regulations.gov*.

Dated: October 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–22926 Filed 10–15–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1127]

Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice entitled ''Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments'' that appeared in the **Federal Register** of June 1, 2020. The notice announced the establishment of a docket to solicit comments on the listing of patent information in the FDA publication, ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (commonly known as the ''Orange Book''). The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice published on June 1, 2020 (85 FR 33169). Submit either electronic or written comments by November 16, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 16, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 16, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–N–1127 for ''Listing of Patent Information in the Orange Book; Establishment of a Public Docket; Request for Comments; Reopening of Comment Period.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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