TABLE 1—SUMMARY OF PROPOSED DATA FIELD CHANGES TO FORM FDA 3926—Continued

Current field:	Includes proposed changes to:	Becoming new field:	With accompanying instruction to:
5: Treatment Information.	Add ''(including rationale for dose)''. Add ''(*e.g.,* assessment criteria/procedure(s) for monitoring and frequency)''. Add ''(*e.g.,* criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment),''. Add ''(*e.g.,* concomitant medication)''. Add ''You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed.''.	Field 6	Provide treatment information, including the investigational drug's name and the name of the entity supplying the drug (generally the manufacturer), the applicable FDA review division (if known), and a concise statement regarding the treatment plan. This includes the planned dose, route and schedule of administration of the investigational drug (including rationale for dose), planned duration of treatment, monitoring procedures (*e.g.,* assessment criteria/procedure(s) for monitoring and frequency), planned modifications to the treatment plan in the event of toxicity (*e.g.,* criteria for adjusting dose if dose reduction or escalation is planned, criteria for stopping the treatment), and other relevant information (*e.g.,* concomitant medication). The information should be entered within the space provided. You may choose to attach an Investigator Brochure, scientific publication(s), or other supporting documents, if needed.
None	Add a box option for ''Request for Withdrawal'' under ''Summary of Expanded Access Use (treatment completed)''.	9. Contents of Submission ..... ☐ Request for Withdrawal.	Field 9: Contents of Submission (Follow-up/Additional Submissions Only). *Request for Withdrawal:* A submission describing the intent to withdraw an effective IND (21 CFR 312.38).
None	Add ''When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted.''.	Field 10.b.: Request for Authorization to Use Alternative IRB Review Procedures.	Select this box to request under 21 CFR 56.105, authorization to obtain concurrence by the IRB chairperson or by a designated IRB member, instead of at a convened IRB meeting, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. When a waiver is requested in this manner, the physician does not receive notice from FDA indicating that the waiver is granted.
None	Add ''Information on where and how to submit this form is available at Expanded Access—How to Submit''.	Field 11: Certification Statement and Signature of the Physician.	Field 11: Certification Statement and Signature of the Physician Information on where and how to submit this form is available at Expanded Access—How to Submit.
[General Instruction?].	Insert a statement ''Information on where and how to submit this form is available at Expanded Access—How to Submit a Request (Forms)'' under ''Signature of Physician'' after Field 11.	[General Instruction?]	Information on where and how to submit this form is available at Expanded Access—How to Submit a Request (Forms).

We retain the currently approved burden estimate of 13,910 responses and 255,326 hours annually for the information collection. We anticipate no adjustment as a result of the proposed form updates and have posted a draft of revised Form FDA 3926 to the docket, available for public inspection through *https://www.regulations.gov.*

Dated: May 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09982 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–E–0675]

Determination of Regulatory Review Period for Purposes of Patent Extension; Detectnet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for Detectnet and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by July 10, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 6, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late,

untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 10, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–E–0675 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; Detectnet.'' 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 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 § 10.20 (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.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product Detectnet (copper Cu-64 dotatate). Detectnet is a radioactive diagnostic agent indicated for use with positron emission tomography for localization of somatostatin receptor positive neuroendocrine tumors in adult patients. Subsequent to this approval, the USPTO received a patent term restoration application for Detectnet (U.S. Patent No. 10,383,961) from Somscan APS, and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated June 13, 2022, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of Detectnet represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for Detectnet is 989 days. Of this time, 744 days occurred during the testing phase of the regulatory review period, while 245 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 21, 2017. The applicant claims November 28, 2017, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was December 21, 2017, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* January 3, 2020. FDA has verified the applicant's claim that the new drug application (NDA) for Detectnet (NDA 213227) was initially submitted on January 3, 2020.

3. *The date the application was approved:* September 3, 2020. FDA has verified the applicant's claim that NDA 213227 was approved on September 3, 2020.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 312 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: May 4, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09891 Filed 5–9–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0973]

Revocation of Three Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Thermo Fisher Scientific Inc., for the OmniPATH COVID–19 Total Antibody ELISA Test; Detect, Inc., for the Detect Covid–19 Test; and Cepheid, for the Xpert Xpress SARS–CoV–2/Flu/RSV. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as requested by each Authorization holder. The revocations, which include an explanation of the reasons for each revocation, are reprinted at the end of this document.

DATES: The Authorization for the Thermo Fisher Scientific Inc.'s OmniPATH COVID–19 Total Antibody ELISA Test is revoked as of April 13, 2023. The Authorization for the Detect, Inc.'s Detect Covid–19 Test is revoked as of April 14, 2023. The Authorization for the Cepheid's Xpert Xpress SARS–CoV–2/Flu/RSV is revoked as of April 17, 2023.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Policy, 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 that office in processing your request or include a fax number to which the revocations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) as amended by the Project BioShield Act of 2004 (Pub. L. 108–276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113–5) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On October 2, 2020, FDA issued the Authorization to Thermo Fisher Scientific Inc., for the OmniPATH COVID–19 Total Antibody ELISA Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. On October 28, 2021, FDA issued the Authorization to Detect, Inc., for the Detect Covid–19 Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on March 22, 2022 (87 FR 16198), as required by section 564(h)(1) of the FD&C Act. On September 24, 2020, FDA issued the Authorization to Cepheid, for the Xpert Xpress SARS–CoV–2/Flu/RSV, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the **Federal Register** on April 23, 2021 (86 FR 21751), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. Authorization Revocation Requests

In a request received by FDA on April 10, 2023, Thermo Fisher Scientific Inc., requested the withdrawal of, and on April 13, 2023, FDA revoked, the Authorization for the Thermo Fisher Scientific Inc.'s OmniPATH COVID–19