U.S. FOOD & DRUG ADMINISTRATION

September 27, 2021

Ashley Vu
Regulatory Affairs Manager
Thermo Fisher Scientific, Inc.
5781 Van Allen Way
Carlsbad, CA 92008
Re: Revocation of EUA210447

Dear Ms. Vu:

This letter is in response to Thermo Fisher Scientific, Inc.'s request on behalf of Life Technologies Corporation (a part of Thermo Fisher Scientific, Inc.) dated September 22, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA210447) for the TaqPath COVID-19 MS2 Combo Kit 2.0 issued on August 2, 2021. Thermo Fisher Scientific, Inc. indicated that it has decided to not commercially support the TaqPath COVID-19 MS2 Combo Kit 2.0 at this time "due to the current public clinical needs being met by our other EUA assays that are available and on market."

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Thermo Fisher Scientific, Inc. has notified FDA that it is longer commercially supporting the TaqPath COVID-19 MS2 Combo Kit 2.0 and requests FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210447 for the TaqPath COVID-19 MS2 Combo Kit 2.0, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the TaqPath COVID-19 MS2 Combo Kit 2.0 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23500 Filed 10–27–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1050]

Agency Information Collection Activities; Proposed Collection; Comment Request; Targeted Mechanism of Action Presentations in Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice

solicits comments on a proposed study entitled ''Targeted Mechanism of Action Presentations in Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by December 27, 2021.

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 December 27, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 27, 2021. 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–2021–N–1050 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Targeted Mechanism of Action Presentations in Prescription Drug Promotion.'' 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 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

For copies of the questionnaire: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCResearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Targeted Mechanism of Action Presentations in Prescription Drug Promotion

OMB Control Number 0910—NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

The Office of Prescription Drug Promotion's (OPDP) mission is to

protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience, and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas, advertising features and target populations.

Because we recognize the strength of data and the confidence in the robust nature of the findings are improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other scientific sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page, which can be found at: *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

In 2014, OPDP conducted focus groups designed to provide insights on how consumers and healthcare providers (HCP), including physicians, nurse practitioners, and physician assistants, interpret the term ''targeted'' in prescription drug promotional materials. Although diverse views were voiced, there appeared to be some tendency toward the impression that products with promotional materials using this term would be safer and more effective than other similar treatments. OPDP is also now conducting a nationally representative survey regarding the ways in which consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotional materials, including assessment of impressions of the terms ''targeted'' and ''targeted mechanism of action'' (targeted MoA) (May 10, 2021, 86 FR 24867). Building upon this line of research, the proposed study will investigate the influence of targeted MoA claims, graphics, and disclosures that provide context about a drug's targeted MoA, utilizing an experimental design with both consumer and HCP samples. The experimental approach described here is intended to complement and augment the prior research by facilitating assessment of causality. Specifically, the proposed study will explore how varied targeted MoA presentations affect consumer and HCP understanding of the MoA of a drug, perception of drug benefits and risks, attention to risk information, and interest in the drug.

Table 1 depicts the study design. Participants will be randomly assigned to 1 of 12 experimental conditions in which the presence versus absence of: (1) A targeted MoA claim, (2) a graphic depicting a targeted MoA, and (3) a disclosure that provides context about the targeted MoA of the drug are varied in a branded website for a fictitious prescription drug indicated to treat bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra) that have spread or cannot be removed by surgery. We selected cancer as the medical condition for study given the prevalence of targeted MoA presentations in promotional materials for prescription drugs indicated to treat various forms of cancer. Notably, there will be three variations related to the targeted MoA graphic: (1) No graphic, (2) an inaccurate graphic (graphic 1) showing only the effect of the drug on cancerous cells but not on healthy cells, and (3) an accurate graphic (graphic 2) that will show the effect of the drug on both cancerous and healthy cells. The design will be replicated in both the consumer and HCP samples with stimuli specifically created for each audience. Draft stimuli were informed by, but not identical to, actual targeted MoA presentations from a marketplace evaluation conducted under FDA guidance. Draft stimuli were also informed by an FDA subject matter expert's review. Following exposure to the stimuli, the participants will complete a questionnaire designed to assess relevant outcome measures. A copy of the questionnaire is available upon request. All aspects of this study will be completed online. Participation is estimated to take approximately 20 minutes, excluding the screener's time.

TABLE 1—STUDY DESIGN

Sample	Disclosure	Targeted MoA claim	Targeted MoA graphic [1]		
			Present (graphic 1—inaccurate)	Present (graphic 2—accurate)	Absent
HCP	Present	Present	■	■	■
		Absent	■	■	■
	Absent	Present	■	■	■
		Absent	■	■	■
Consumer	Present	Present	■	■	■
		Absent	■	■	■
	Absent	Present	■	■	■
		Absent	■	■	■

[1] Each ■ symbol represents an experimental condition.

For the HCP sample, we will recruit oncologists, PCPs with oncology experience, and nurse practitioners and physician assistants who specialize in oncology. We will also recruit a general population sample of adult volunteers 18 years or older for the consumer sample. A general population, rather than a diagnosed consumer sample, was

selected because of concerns about being able to recruit a sufficient number of participants for this particular study if we selected a cancer-specific sample.

We will ask consumers to consider a hypothetical scenario in which they have recently been diagnosed with cancer and are actively looking for available treatments. HCPs will be asked to consider a scenario in which they are actively looking for available treatments for a patient who has been diagnosed with cancer. We will also ask consumers if they have ever been diagnosed with cancer. HCP participants will be drawn from online HCP panels and general population consumer participants will be drawn from online consumer panels. Informed by power analyses, we will recruit a sample of 540 HCPs and 540 consumers for the main study.

FDA estimates the burden of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents [2]	Number of responses per respondent	Total annual responses	Average burden per response [3]	Total hours
Pretest					
General population: Pretest screener completes (assumes 75% eligible)	528	1	528	0.08 (5 minutes)	42.2
General population: Number of completes, pretest	396	1	396	0.33 (20 minutes)	130.7
HCP: Pretest screener completes (assumes 60% eligible)	660	1	660	0.08 (5 minutes)	52.8
HCP: Number of completes, pretest	396	1	396	0.33 (20 minutes)	130.7
Main Study					
General population: Number of main study screener completes (assumes 75% eligible)	792	1	792	0.08 (5 minutes)	63.4
General population: Number of completes, main study	594	1	594	0.33 (20 minutes)	196.0
HCP: Number of main study screener completes (assumes 60% eligible)	990	1	990	0.08 (5 minutes)	79.2
HCP: Number of completes, main study	594	1	594	0.33 (20 minutes)	196.0
Total					891

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.
[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23507 Filed 10–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1584]

Authorization of Emergency Use of Certain Medical Devices During COVID–19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID–19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID–19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID–19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, 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 Authorization may be sent.