



FDA U.S. FOOD & DRUG
ADMINISTRATION

February 24, 2022

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074
Re: Revocation of EUA210272

Dear Ms. Drysdale:

This letter is in response to the request from Abbott Diagnostics Scarborough, Inc. ("Abbott"), received via email on February 21, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test issued on March 31, 2021 and amended on September 23, 2021 and January 7, 2022. FDA understands no product was distributed under the EUA. Abbott indicated that authorization of the BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required, in consideration of Abbott's product available under another EUA issued to Abbott.

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 Abbott has notified FDA that the EUA for BinaxNOW COVID-19 Ag Card 2 Home Test is no longer required and requested FDA revoke the EUA for the BinaxNOW COVID-19 Ag Card 2 Home Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210272 for the BinaxNOW COVID-19 Ag Card 2 Home Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BinaxNOW COVID-19 Ag Card 2 Home Test 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/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Dated: March 15, 2022.

Andi Lipstein Fristedt,

*Deputy Commissioner for Policy, Legislation,
and International Affairs, U.S. Food and Drug
Administration.*

[FR Doc. 2022-05892 Filed 3-18-22; 8:45 am]

BILLING CODE 4164-01-C

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA-2013-N-0093]

**Agency Information Collection
Activities; Proposed Collection;
Comment Request; New Molecular
Entity New Drug Applications and
Original Biologics License
Applications**

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in

response to the notice. This notice solicits comments on information collection associated with evaluating FDA's program for Enhanced Review Transparency and Communication (the Program) of new molecular entity new drug applications and original biologics license applications (BLAs).

DATES: Submit either electronic or written comments on the collection of information by May 20, 2022.

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 May 20, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 20, 2022. 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-2013-N-0093 for "New Molecular Entity New Drug Applications and Original Biologics License Applications." 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: Domini Bean, Office of Operations,

Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRASStaff@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, including each proposed extension of an existing 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.

Evaluation of the Program for Enhanced Review Transparency and Communication for New Molecular Entity New Drug Applications and Original 351(a) Biologics License Applications in Prescription Drug User Fee Acts and 351(k) Biologics License Applications in Biosimilar User Fee Acts

OMB Control Number 0910-0746—Extension

This information collection supports the evaluation of certain performance goals and procedures set forth in what is known as FDA's "goals letter" or "commitment letter" under the sixth authorization of the Prescription Drug User Fee Act (PDUFA VI) and the

second authorization of the Biosimilar User Fee Act (BsUFA II). The goals letters are the result of Agency, industry, and public input, as Congressionally mandated under the applicable statutes. The documents entitled “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,” and “Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022” represent current performance goals agreed to by FDA in support of these respective programs. These documents are available at: <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf>; and <https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf>. Work to reauthorize

these authorities from Fiscal Years 2023 to 2027 is ongoing.

To implement certain performance goals, we established the Program to promote greater transparency and increased communication between the FDA review team and the applicant on the most innovative products that we review. The Program goals are intended to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval so that patients have timely access to safe, effective, and high-quality new drugs and biologics. A key aspect of the extension of the Program to BsUFA II is to conduct an interim and final assessment that will evaluate how well the parameters of the Program have achieved the intended goals. Based on sponsors’ responses and other data, on

December 2, 2020, we published an interim report that is available on FDA’s website at <https://www.fda.gov/media/144130/download>. We learned that under BsUFA II review, teams have been effective in enhancing review transparency and communication, with milestone meetings also enhancing the predictability of the review process. We have also adapted certain good practices identified through the Program, including providing pre-submission advice and templates; allocating time for applicant-identified discussion topics in late-cycle meetings where feasible; and recommending request response times of greater than 2 days for applicants with a global presence. We expect to continue these assessments.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	5	1	5	1.5	7.5
Interviews	75	1	75	1.5	112.5
Total			80		120

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We plan interviews with up to three applicant representatives per each 351(k) BLA first-cycle action issued for applications reviewed under the Program. In addition, a pretest of the interview protocol with five respondents will also be conducted. Based on our prior experience with the Program and communications with the regulated industry, we assume that five applicant representatives will expend approximately 1.5 hours to complete the pretest, for a total of 7.5 burden hours. We further assume that up to 75 applicant representatives (up to 3 representatives for each of up to 25 applications) will participate in the post-action interviews each year and that each interview will last approximately 1.5 hours, for a total of 120 burden hours. Cumulatively, we estimate an overall decrease to the information collection, which corresponds to a decrease in submissions received by the Agency over the last 3 years.

Dated: March 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–05814 Filed 3–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Topics in Alzheimer’s Disease, Mild Cognitive Impairment and Cognitive Aging, March 25, 2022, 10:00 a.m. to March 25, 2022, 8:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on March 03, 2022, FR Doc. 2022–04426, 87 FR 12182.

This meeting is being amended to change the Contact Person from Maribeth Champoux to Heidi Friedman, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 301–379–5623. The meeting is closed to the public.

March 15, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–05835 Filed 3–18–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, March 29, 2022, 1:00 p.m. to 6:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on March 04, 2022, V 87 #43 Page 12467, FR Doc No. 2022–04619.

Meeting is being amended to change the Contact Person from Ai-Ping Zou to David Jollie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health. The meeting is closed to the public.

Dated: March 16, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–05896 Filed 3–18–22; 8:45 am]

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