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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