

reconsidered codes by early October 2021, electronically to our CLFS dedicated email box, *CLFS\_Annual\_Public\_Meeting@cms.hhs.gov* (the specific date for the publication of the determinations on the CMS website, as well as the deadline for submitting comments regarding the determinations, will be published on the CMS website). Final determinations for new test codes to be included for payment on the CLFS for CY 2022 and reconsidered codes will be posted our website in November 2021, along with the rationale for each determination, the data on which the determinations are based, and responses to comments and suggestions received from the public. The final determinations with respect to reconsidered codes are not subject to further reconsideration. With respect to the final determinations for new test codes, the public may request reconsideration of the basis and amount of payment as set forth in § 414.509.

### III. Registration Instructions

The Division of Ambulatory Services in the CMS Center for Medicare is coordinating the CLFS Annual Public Meeting registration. Beginning May 3, 2021 and ending June 3, 2021, registration may be completed by presenters only. Individuals who intend to view and/or listen to the meeting do not need to register. Presenter registration may be completed by sending an email to our CLFS dedicated email box, *CLFS\_Annual\_Public\_Meeting@cms.hhs.gov*. The subject of the email should state "Presenter Registration for CY 2021 CLFS Annual Laboratory Meeting." All of the following information must be submitted when registering:

- Speaker name.
- Organization or company name.
- Telephone numbers.
- Email address that will be used by the presenter in order to connect to the virtual meeting.
  - New or Reconsidered Code (s) for which presentation is being submitted.
  - Presentation.

Registration details may not be revised once they are submitted. If registration details require changes, a new registration entry must be submitted by the date specified in the **DATES** section of this notice. Additionally, registration information must reflect individual-level content and not reflect an organization entry. Also, each individual may only register one person at a time. That is, one individual may not register multiple individuals at the same time.

After registering, a confirmation email will be sent upon receipt of the

registration. The email will provide information to the presenter in preparation for the meeting. Registration is only required for individuals giving a presentation during the meeting. Presenters must register by the deadline specified in the **DATES** section of this notice.

If you are not presenting during the CLFS Annual Public Meeting, you may view the meeting via webinar or listen-only by teleconference. If you would like to listen to or view the meeting, teleconference dial-in and webinar information will appear on the final CLFS Annual Public Meeting agenda, which will be posted on the CMS website when available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html?redirect=/ClinicalLabFeeSched/>.

### IV. Special Accommodations

Individuals viewing or listening to the meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance, should send an email to the resource box (*CDLT\_Annual\_Public\_Meeting@cms.hhs.gov*). The deadline for submitting this request is listed in the **DATES** section of this notice.

### V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, 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: April 28, 2021.

**Lynette Wilson**,

*Federal Register Liaison, Centers for Medicare & Medicaid Services.*

[FR Doc. 2021-09260 Filed 4-30-21; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-Z-0025]

#### Withdrawal of Notice Regarding the Food and Drug Administration Drug Review Timeline Transparency; Revocation of Statement of Policy

**AGENCY:** Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

**ACTION:** Notice; withdrawal; statement of policy; revocation.

**SUMMARY:** The Department of Health and Human Services (Department or HHS) and the Food and Drug Administration (FDA or Agency) are issuing this notice to withdraw the notice published in the **Federal Register** of January 15, 2021, announcing a Statement of Policy indicating that FDA will publish certain information regarding the timeline for its review of drug product applications. The Department and FDA are withdrawing the notice and revoking the Statement of Policy because, among other things, the notice did not account for all relevant considerations related to information that is already publicly available about FDA's review of drug applications.

**DATES:** The notice is withdrawn and the Statement of Policy is revoked as of May 3, 2021.

#### FOR FURTHER INFORMATION CONTACT:

Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993-0002, 301-348-3035.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 15, 2021 (86 FR 4083), HHS published a notice entitled "FDA Drug Review Timeline Transparency; Statement of Policy" (Statement of Policy). The Statement of Policy described the Department's review of application timelines and directed FDA to publish annually on its website, for each approved new drug application (NDA) and abbreviated new drug application (ANDA) approved after the date of the **Federal Register** notice: "(a) the date on which FDA 'filed,' in the case of an NDA, or 'received,' in the case of an ANDA, such application; (b) the date on which FDA approved the NDA or ANDA; (c) the total days elapsed between the dates in (a) and (b); and (d) the total days in excess of 180-days the date of (c)." We did not find any evidence that HHS consulted with, otherwise involved, or even notified

FDA before issuing the notice. Section 1003(d) (21 U.S.C. 393(d)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides that the Secretary “shall be responsible for executing” the FD&C Act “through the [FDA] Commissioner.” Here, the notice in directing FDA to report on whether the Agency’s action on drug applications met statutory timelines is clearly an action “executing” the FD&C Act.

Upon further consideration, the Department and FDA have determined that the Statement of Policy did not account for all relevant considerations related to the timing of FDA’s review of drug applications. The Statement of Policy did not accurately account for the time that the review period for drug applications starts. Although the table of drug approvals presented in the Statement of Policy (86 FR 4083 at 4083–4084) references the drug application submission date as the beginning of a 180-day review period, the review period does not actually start until a drug application is “filed” or “received” by FDA (see section 505(c)(1) and (j)(5)(A) of the FD&C Act (21 U.S.C. 355(c)(1) and (j)(5)(A))). Under FDA’s regulations, an NDA is not filed until FDA has made a threshold determination that the NDA is sufficiently complete to permit a substantive review. For NDAs, FDA will determine whether the application may be filed within 60 days (see § 314.101(a)(1) (21 CFR 314.101(a)(1))). If the application is filed, the regulation states that the “date of filing will be the date 60 days after the date FDA received the NDA. The date of filing begins the 180-day period described in section 505(c) of the Federal Food, Drug, and Cosmetic Act” (§ 314.101(a)(2)). An ANDA is not received until FDA has made a threshold determination that the ANDA is substantially complete (§ 314.101(b)(1)). If the ANDA is received, the date of receipt is then considered to be the date of submission (§ 314.101(b)(2)).

Moreover, the 180-day review period can be extended by mutual agreement between FDA and an applicant (see section 505(c)(1) and (j)(5)(A) of the FD&C Act; § 314.100(c)). For instance, an applicant that receives a complete response letter from FDA may choose to respond to the complete response letter (rather than requesting an opportunity for a hearing), thus agreeing to extend the 180-day review period (see 21 CFR 314.110(b)–(c) and 314.101(f)). We also note that since the enactment of the Prescription Drug User Fee Act of 1992 (PDUFA), there has been a mutual understanding between industry and the Agency that the review cycle for an

application or supplement subject to user fees may be adjusted (either shortened or lengthened) in accordance with the user fee performance goals (see “Applications for Approval to Market a New Drug; Complete Response Letter; Amendments to Unapproved Applications,” 73 FR 39588 at 39593 (July 10, 2008)). A similar understanding exists between industry and the Agency with respect to the review of generic drug applications under the Generic Drug User Fee Amendments (GDUFA).

Further, the Department and FDA have determined that the Statement of Policy did not take into account all of the relevant considerations related to the timeframe for FDA’s review of drug applications. For instance, the Statement of Policy did not fully consider PDUFA and GDUFA. The sixth reauthorization of PDUFA and the second reauthorization of GDUFA reference performance goals transmitted by the Secretary of HHS to Congress in commitment letters,<sup>1</sup> which represent the result of FDA’s discussions with the regulated industry and public stakeholders. The performance goals and other commitments specified in these letters apply to aspects of the drug review programs that are important for facilitating timely access to safe and effective medicines for patients. The commitment letters include goals for the timeline of the review of drug applications, and FDA regularly meets or exceeds these goals.

FDA’s approval of drugs benefits American consumers, who have access to one of the safest and most advanced pharmaceutical systems in the world. Under PDUFA, FDA has significantly reduced the time it takes to evaluate new drugs and biologics without compromising its rigorous standards for a demonstration of safety, efficacy, and quality of new drugs and biologics before approval.<sup>2</sup> The efficiency gains under PDUFA have revolutionized the drug review process in the United States and enabled FDA to ensure more timely access to innovative and important new therapies for patients.<sup>3</sup> FDA also understands that high drug prices have a direct impact on patients. The processes under GDUFA continue to help reduce review times and approval times, boosting competition and helping to ensure that safe, effective, high-

quality generic drug products are available to the American public.<sup>4</sup>

Transparency and accountability will not be sacrificed in the absence of the Statement of Policy since such information is already publicly available. PDUFA and GDUFA require the HHS Secretary to submit annual performance reports to Congress for each fiscal year during which fees are collected (see sections 736B(a) and 744C(a) of the FD&C Act (21 U.S.C. 379h–2(a) and 379j–43(a))). Annual performance reports document FDA performance in meeting goals in the commitment letters agreed to by the HHS Secretary, including goals for the timeline of the review of drug applications. These reports are required to be publicly available and posted on FDA’s website (sections 736B(e) and 744C(e) of the FD&C Act), and they are available at <https://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports> (PDUFA) and <https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports> (GDUFA). In addition, as part of FDARA and its GDUFA II commitments (see section 807 of FDARA and section VI(C)(1) and (2) of the GDUFA Reauthorization Performance Goals and Program Enhancements for Fiscal Years 2018–2022, available at <https://www.fda.gov/media/101052/download>), FDA publishes monthly metrics on its website that include the number of applications approved and tentatively approved and quarterly metrics that include the mean and median approval and tentative approval times, available at <https://www.fda.gov/industry/generic-drug-user-fee-amendments/enhanced-accountability-reporting>. Thus, the review timeline information the Statement of Policy sought to have FDA provide publicly would be redundant with information that is already publicly available.

Therefore, the **Federal Register** notice announcing the Statement of Policy published on January 15, 2021, is withdrawn and the Statement of Policy is revoked.

<sup>1</sup> See sections 101(b) and 301(b) of FDA Reauthorization Act of 2017, Public Law 115–52 (FDARA).

<sup>2</sup> See FDA’s Annual PDUFA Performance Reports available at: <https://www.fda.gov/about-fda/user-fee-performance-reports/pdufa-performance-reports>.

<sup>3</sup> Id.

<sup>4</sup> See FDA’s Annual GDUFA Performance Reports available at: <https://www.fda.gov/about-fda/user-fee-performance-reports/gdufa-performance-reports>.

Dated: April 23, 2021.

**Janet Woodcock,**

*Acting Commissioner of Food and Drugs.*

Dated: April 27, 2021.

**Xavier Becerra,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021-09134 Filed 4-30-21; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Request for Information (RFI) Developing the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans; Correction

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice; correction.

**SUMMARY:** The Office of the Assistant Secretary for Health published a document in the *Federal Register* of April 27, 2021, requesting comments be sent via [www.regulations.gov](http://www.regulations.gov) with a docket number of HHS-OASH-2021-0001. The referenced docket number was incorrect and also inadvertently omitted two additional questions on page 22215.

**FOR FURTHER INFORMATION CONTACT:** Dr. Kristen Honey, Chief Data Scientist, Senior Advisor, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, [vectorbornedisease@hhs.gov](mailto:vectorbornedisease@hhs.gov), (202) 853-7680.

#### SUPPLEMENTARY INFORMATION:

##### Correction

In the *Federal Register* of April 27, 2021, in FR Doc. 2021-08167, on page 22214, in the third column, correct the **ADDRESSES** caption to read:

**ADDRESSES:** Public comments should be submitted online at <http://www.regulations.gov>. All submissions must be submitted to the Docket named HHS-OASH-2021-0012 to "Request for Information (RFI) from Non-Federal Stakeholders: Developing the National Public Health Strategy for the Prevention and Control of Vector-Borne Diseases in Humans." Comments submitted electronically, including attachments, will be posted to the docket unchanged and available for view by the public. Evidence and information supporting your comment can be submitted as attachments. Please provide your contact information or

organization name on the web-based form for possible follow up from HHS. There is a 5,000 character limit on comments and maximum number (10) of attached files and maximum size (10 MB) of each attached file.

In the *Federal Register* of April 27, 2021, in FR Doc. 2021-08167, on page 22215, in the second column, after question number "4." should be two additional questions to read as follows:

5. How can insights from climate change be incorporated into the development of a national strategy?

6. How should low-income and vulnerable populations be addressed in the national strategy?

**Kristen Honey,**

*Chief Data Scientist, Senior Advisor, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services.*

[FR Doc. 2021-09241 Filed 4-30-21; 8:45 am]

**BILLING CODE 4150-28-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Heart, Lung, and Blood Initial Review Group; Clinical Trials Review Committee.

*Date:* June 24, 2021.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

*Contact Person:* Keary A. Cope, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209-A, Bethesda, MD 20892-7924, (301) 827-7912, [copeka@mail.nih.gov](mailto:copeka@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung

Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 28, 2021.

**David W Freeman,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021-09236 Filed 4-30-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Biology Structure and Regeneration Study Section.

*Date:* June 2-4, 2021.

*Time:* 9:00 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, (301) 451-0996, [ybi@csr.nih.gov](mailto:ybi@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA RM20-022: Faculty Institutional Recruitment for Sustainable Transformation (FIRST) Program.

*Date:* June 2-3, 2021.

*Time:* 9:30 a.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Elia K Ortenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3108, MSC 7816, Bethesda, MD 20892, (301) 827-7189, [femiaee@csr.nih.gov](mailto:femiaee@csr.nih.gov).

*Name of Committee:* Brain Disorders and Clinical Neuroscience Integrated Review