



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

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DATES: The notice is withdrawn and the Statement of Policy is revoked as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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,¹ 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

¹ See sections 101(b) and 301(b) of FDA Reauthorization Act of 2017, Pub. L. 115-52 (FDARA).

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.² 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.³ 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.⁴

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

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

³ Id.

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

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.

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.

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