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Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

FDA Drug Review Timeline Transparency; Statement of Policy

The Department and its component agencies exist to serve the American people. Consistent with and in follow up to the Department's previous transparency efforts,[1] and given the significant impact FDA's approval of drugs has on Americans, the Secretary believes the public would benefit from information regarding the timeline for FDA's review of drug product applications as provided in this document.

In 1962, Congress amended the Food, Drug, and Cosmetic Act (FD&C Act) to authorize the Food and Drug Administration (FDA) to review and approve ''new drugs'' for safety and efficacy.[2] When Congress made this historic change to our nation's drug laws, it provided a timeframe for FDA's review. In section 104 of the Drug Amendments of 1962, codified at section 505(c) of the FD&C Act, 21 U.S.C. 355(c), Congress required that, for New Drug Applications (NDAs), ''[w]ithin one hundred eighty days after the filing of an application . . . , the Secretary shall either approve the application . . . or give the applicant notice of an opportunity for a hearing before the Secretary.'' As the Senate Judiciary Committee explained at the time, ''this provision strikes a balance between the need for governmental control to assure that new drugs are not placed on the market until they have passed the relevant tests and the need to insure that governmental control does not become so rigid that the flow of new drugs to the market, and the incentive to undergo the expense involved in preparing them for the market, become stifled.'' [3]

At the time, the 180-day timeframe for review of ''new drugs'' was uncontroversial. At a 1963 public hearing, the Acting Director for FDA's Division of New Drugs stated that ''[a]pplications for drugs of questionable safety or effectiveness will continue to take more of every body's time.'' [4] However, the Director ''pledge[d] action greatly short of the 180-day limit on all applications and supplements that present good scientific evidence of the safety and effectiveness of the drugs and that are properly informative to the physician or patient.'' [5]

When Congress made additional amendments to the FD&C Act in 1984, it borrowed from and applied the existing 180-day review framework to the review of Abbreviated New Drug Applications (ANDAs), the approval mechanism for generic drugs.[6] Under section 505(j)(5)(A) of the FD&C Act, 21 U.S.C. 355(j)(5)(A), the Secretary ''shall approve or disapprove the [ANDA] application'' ''[w]ithin one hundred and eighty days of the initial receipt of an application.'' FDA promulgated regulations implementing the 180-day statutory provisions for review of NDAs and ANDAs. *See* 21 CFR 314.100, 314.101. While the Prescription Drug User Fee Act (PDUFA) and Generic Drug User Fee Act (GDUFA) in their iterative forms have provided FDA with additional resources to carry out its statutory mission, Congress did not do away with the 180-day provisions in section 505 of the FD&C Act, 21 U.S.C. 355, in those laws.

Though the agency has made strides over the years to expedite review in the face of limited resources, the total time elapsed between FDA's filing of an NDA or receipt of an ANDA to ultimate approval or disapproval of the application often exceeds 180 days. Even so, reporting on drug approvals, such as GAO's March 2020 report,[7] focused primarily on agency compliance with PDUFA dates. The GAO report did not mention the 180-day benchmark or discuss the agency's approval timeframe in view of that requirement.

Given this gap in reporting, the Department reviewed FDA's New Drug Therapy Approvals from 2019 [8] in view of the 180-day timeframe. The Department's review considered 48 products listed by the agency as approved in 2019.[9] The table below presents, among other things, the date of submission, date of approval, total days from submission to approval, and total days in excess of 180 days of submission for these drugs.

Drug brand name	Summary of FDA-approved use on approval date	Submission date	Approval date	Days submission to approval	Days in excess of 180 days
Accrufer	Iron deficiency anemia	9/27/2018	7/25/2019	301	121
Adakveo	Reduce vasoocclusive crises in sickle cell disease.	5/16/2019	11/15/2019	183	3
Aklief	Acne vulgaris	10/4/2018	10/4/2019	365	185
Balversa	Locally advanced or metastatic bladder cancer	9/18/2018	4/12/2019	206	26
Beovu	Wet age-related macular degeneration	2/7/2019	10/7/2019	242	62
Brukinsa	Mantle cell lymphoma	6/27/2019	11/14/2019	140	N/A
Cablivi	Acquired thrombotic thrombocytopenic purpura	6/6/2018	2/6/2019	245	65
Caplyta	Schizophrenia	9/27/2018	12/20/2019	449	269
Dayvigo	Insomnia	12/27/2018	12/20/2019	358	178
Egaten	Fascioliasis	6/14/2018	2/13/2019	244	64
Enhertu	Metastatic breast cancer	8/29/2019	12/20/2019	113	N/A
Evenity	Osteoporosis	7/9/2018	4/9/2019	274	94
ExEm Foam	Diagnostic agent for fallopian tube assessment	10/9/2018	11/7/2019	394	214
Fetroja	Complicated urinary tract infection	12/14/2018	11/14/2019	335	155
fluorodopa F 18	Diagnostic agent for Parkinsonian syndromes	4/10/2019	10/10/2019	183	3

[1] E.g., 85 FR 75893 (Nov. 27, 2020).

[2] Drug Amendments of 1962, Pub. L. 87–781, 76 Stat. 780 (Oct. 10, 1962).

[3] 1962 U.S.C.C.A.N. 2884, 2891.

[4] Proceedings, FDA Conference on the Kefauver-Harris Drug Amendments and Proposed Regulations, at 7 (Feb. 15, 1963).

[5] *Id.* at 6.

[6] Drug Price Competition and Patent Term Restoration Act of 1984, Public Law 98–417, 98 Stat. 1585, 1588 (Sept. 24, 1984).

[7] GAO, *FDA Drug Approval, Application Review Times Largely Reflect Agency Goals* (Mar. 2020), *https://www.gao.gov/assets/710/705193.pdf.*

[8] FDA, *New Drug Therapy Approvals 2019, https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019.*

[9] In its review, the Department obtained the ''submission date'' (or, if available, ''filing date'') of the 48 drugs by searching documents available to the public on FDA's Drugs@FDA website.

Drug brand name	Summary of FDA-approved use on approval date	Submission date	Approval date	Days submission to approval	Days in excess of 180 days
Ga 68 DOTATOC	Diagnostic agent for neuroendocrine tumors	5/23/2018	8/21/2019	455	275
Givlaari	Acute hepatic porphyria	6/4/2019	11/20/2019	169	N/A
Ibsrela	Irritable bowel syndrome with constipation	9/12/2018	9/12/2019	365	185
Inrebic	Certain types of myelofibrosis	1/4/2019	8/16/2019	224	44
Jeuveau	Improve appearance of glabellar lines (lines between eyebrows).	5/15/2017	2/1/2019	627	447
Mayzent	Relapsing forms of multiple sclerosis	6/28/2018	3/26/2019	271	91
Nourianz	Parkinson's disease ''off'' episodes	7/27/2019	8/27/2019	31	N/A
Nubeqa	Non-metastatic prostate cancer	2/26/2019	7/30/2019	154	N/A
Oxbryta	Sickle cell disease	6/26/2019	11/25/2019	152	N/A
Padcev	Refractory bladder cancer	7/15/2019	12/18/2019	146	N/A
Piqray	Advanced or metastatic breast cancer	12/18/2018	5/24/2019	157	N/A
Polivy	Relapsed or refractory diffuse large B-cell lymphoma.	12/19/2018	6/10/2019	173	N/A
pretomanid	Treatment-resistant forms of tuberculosis	12/14/2018	8/14/2019	243	63
Reblozyl	Anemia associated with beta thalassemia	4/4/2019	11/8/2019	218	38
Recarbrio	Complicated urinary tract infections and complicated intra-abdominal infections	11/16/2018	7/16/2019	242	62
Reyvow	Migraine with or without aura	10/11/2018	10/11/2019	365	185
Rinvoq	Moderately to severely active rheumatoid arthritis.	12/18/2018	8/16/2019	241	61
Rozlytrek	Metastatic non-small cell lung cancer and locally advanced or metastatic solid tumors with a specific genetic defect.	12/18/2018	8/15/2019	240	60
Scenesse	Increase pain-free light exposure in patients with erythropoietic protoporphyria.	11/8/2018	10/8/2019	334	154
Skyrizi	Moderate-to-severe plaque psoriasis	4/3/2018	4/23/2019	385	205
Sunosi	Excessive daytime sleepiness in patients with narcolepsy or obstructive sleep apnea.	12/20/2017	3/20/2019	455	275
TissueBlue	Dye used in eye surgery	4/29/2019	12/20/2019	235	55
Trikafta	Cystic Fibrosis	7/19/2019	10/21/2019	94	N/A
Turalio	Symptomatic tenosynovial giant cell tumor	12/3/2018	8/2/2019	242	62
Ubrelvy	Migraine	12/26/2018	12/23/2019	362	182
Vyleesi	Hypoactive sexual desire disorder in premenopausal women.	3/23/2018	6/21/2019	455	275
Vyndaqel	Cardiomyopathy caused by transthyretin-mediated amyloidosis.	11/2/2018	5/3/2019	182	2
Vyondys 53	Duchenne muscular dystrophy	12/19/2018	12/12/2019	358	178
Wakix	Excessive daytime sleepiness in patients with narcolepsy.	12/14/2018	8/14/2019	243	63
Xcopri	Partial-onset seizures	11/21/2018	11/21/2019	365	185
Xenleta	Community-acquired bacterial pneumonia	12/19/2018	8/19/2019	243	63
Xpovio	Relapsed or refractory multiple myeloma	8/6/2018	7/3/2019	331	151
Zulresso	Postpartum depression	4/9/2018	3/19/2019	344	164

The Department found that 38 of the 48 drugs (79.1%) were approved more than 180 days after submission of an application. The average time from submission to approval for the 48 drugs in the table above was 273.8 days. It should be noted that in many instances the failure to meet the 180-day statutory benchmark may have been justified and in such cases, was frequently the result of questions by the agency and responses by the applicant.

Because FDA's approval of drugs affects the health and financial well-being of all Americans, the Department believes the public is entitled to information like the data provided in the table above regarding the amount of the time required for FDA review and approval of new and generic drugs. To that end, effective upon publication of this Notice, for all NDA and ANDA approvals, FDA must take the following action.

FDA shall publish annually on its website, for each approved NDA and ANDA approved after the date of this publication, (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). For example, if an NDA was ''filed'' on January 25, 2021 and approved on December 27, 2021, then the total days elapsed for review would be 336 days, and the days in excess of 180 days would be 156 days.

Members of the public can use this information to further study the health and economic impacts of FDA review timelines. This reporting is also consistent with FDA's mission to ''promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner.'' 21 U.S.C. 393(b)(1). In addition to educating the public, the Department believes this information will inform Congress as to whether to provide FDA with additional resources to carry out the agency's review obligations within the timeframe prescribed by Congress.

Dated: January 8, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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