use of immunizing agents. In addition, under 42 U.S.C. 1396s, the committee is mandated to establish and periodically review and, as appropriate, revise the list of vaccines for administration to vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters to be Considered: The agenda will include discussions on COVID–19 vaccines. No recommendation vote is scheduled for COVID–19 vaccines. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda visit *https://www.cdc.gov/vaccines/acip/meetings/meetings-info.html.*

Meeting Information: The meeting will be webcast live via the World Wide Web; for more information on ACIP please visit the ACIP website: *http://www.cdc.gov/vaccines/acip/index.html.*

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials are part of the public record and are subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket. CDC does not accept comment by email.

Written Public Comment: Written comments must be received on or before January 27, 2021. Oral Public Comment: This meeting will include time for members of the public to make an oral comment. Oral public comment will occur before any scheduled votes including all votes relevant to the ACIP's Affordable Care Act and Vaccines for Children Program roles. Priority will be given to individuals who submit a request to make an oral public comment before the meeting according to the procedures below.

Procedure for Oral Public Comment: All persons interested in making an oral public comment at the January 27, 2021 ACIP meeting must submit a request at *http://www.cdc.gov/vaccines/acip/meetings/* no later than 11:59 p.m., EST, January 25, 2021 according to the instructions provided.

If the number of persons requesting to speak is greater than can be reasonably accommodated during the scheduled time, CDC will conduct a lottery to determine the speakers for the scheduled public comment session. CDC staff will notify individuals regarding their request to speak by email by January 26, 2021. To accommodate the significant interest in participation in the oral public comment session of ACIP meetings, each speaker will be limited to 3 minutes, and each speaker may only speak once per meeting.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–00870 Filed 1–12–21; 4:15 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2306]

TG United Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 16, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040083	Phentermine Hydrochloride (HCl) Capsules, 30 milligrams (mg)	TG United Inc., 16275 Aviation Loop Dr., Brooksville, FL 34604.
ANDA 040451	Cyanocobalamin Injection, 1 mg/milliliters (mL)	Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 040518	Bethanechol Chloride Tablets, 50 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC, 6451 W. Main St., Morton Grove, IL 60053.
ANDA 040532	Bethanechol Chloride Tablets, 5 mg	Do.

Application No.	Drug	Applicant
ANDA 060347	Tetracycline HCl Capsules, 250 mg	Pharmacia & Upjohn Co., a subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 060478	Neomycin Sulfate Ophthalmic Ointment	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
ANDA 065266	Clarithromycin Tablets, 250 mg and 500 mg	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC.
ANDA 065281	Doxycycline Hyclate Delayed Release Capsules, Equivalent to (EQ) 75 mg base; EQ 100 mg base.	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 075208	Ranitidine HCl Tablets, EQ 150 mg base; EQ 300 mg base	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC.
ANDA 075822	Loratadine Orally Disintegrating Tablets, 10 mg	GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, 184 Liberty Corner Rd., Suite 200, Warren, NJ 07059.
ANDA 076760	Ranitidine HCl Tablets, EQ 75 mg base	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC.
ANDA 076849	Vinorelbine Tartrate Injection, EQ 10 mg base/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
ANDA 077432	Carboplatin Injection, 50 mg/5 mL(10 mg/mL), 150 mg/15 mL (10 mg/mL), and 450 mg/45 mL (10 mg/mL).	Do.
ANDA 078500	Amlodipine Besylate Tablets, EQ 2.5 mg base; EQ 5 mg base; EQ 10 mg base.	Morton Grove Pharmaceuticals Inc./Wockhardt USA LLC.
ANDA 084041	Chlordiazepoxide HCl Capsules, 10 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 084678	Chlordiazepoxide HCl Capsules, 5 mg	Do.
ANDA 084679	Chlordiazepoxide HCl Capsules, 25 mg	Do.
ANDA 088508	Homatropine Methylbromide; Hydrocodone Bitartrate Tablets, 1.5 mg; 5 mg.	King Pharmaceuticals Research and Development, LLC, 4000 Centregreen Way, Suite 300, Cary, NC 27513.
ANDA 089953	Thioridazine HCl Tablets, 10 mg, 25 mg, 50 mg, and 100 mg	Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 090094	Didanosine Delayed Release Capsules, 125 mg, 200 mg, 250 mg, and 400 mg.	Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 090394	Iopamidol Injection, 61% and 76%	Sanochemia Corporation USA, 9201 University City Blvd., c/o Countervail Corp., Charlotte, NC 08876.
ANDA 091302	Fludrocortisone Acetate Tablets, 0.1 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 203959	Temozolomide Capsules, 5 mg, 20 mg, 100 mg, 140 mg, and 250 mg.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 425 Privet Rd., Horsham, PA 19044.
ANDA 204243	Indomethacin Extended Release Capsules, 75 mg	Aurobindo Pharma USA, Inc.
ANDA 206061	Pravastatin Sodium Tablets, 20 mg, 40 mg, and 80 mg	Hisun Pharmaceuticals USA, Inc., 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.
ANDA 206857	Tiagabine HCl Tablets, 2 mg, 4 mg, 12 mg, and 16 mg	Wilshire Pharmaceuticals, Inc., 6 Concourse Pkwy., Suite 1800, Atlanta, GA 30328.
ANDA 209076	Ibuprofen Tablets, 200 mg	Ultra Tab Laboratories, Inc., 50 Toc Dr., Highland, NY 12528.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of February 16, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on February 16, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–00833 Filed 1–14–21; 8:45 am]

BILLING CODE 4164–01–P

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.