docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ZYDELIG (idelalisib). As approved in both NDA 206545 and NDA 205858, ZYDELIG is indicated for treatment of patients with:

- Relapsed chronic lymphocytic leukemia in combination with rituximab, in patients for whom rituximab alone would be considered appropriate therapy due to other co-morbidities.
- Relapsed follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies.
- Relapsed small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Accelerated approval was granted for FL and SLL based on overall response rate. Improvement in patient survival or disease related symptoms has not been established. Continued approval for these indications may be contingent upon verification of clinical benefit in confirmatory trials.

Subsequent to the approvals, the USPTO received patent term restoration applications for ZYDELIG (U.S. Patent Nos. RE44599 and RE44638) from ICOS Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated November 4, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approvals of ZYDELIG under NDA 206545 and NDA 205858 represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ZYDELIG is 2,247 days. Of this time, 2,017 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* May 30, 2008. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on May 30, 2008. This is the same IND and the same date FDA determined as the beginning of the regulatory review period for ZYDELIG approved under NDA 205858. The regulatory review period for ZYDELIG approved under NDA 205858 is publishing in this issue of the **Federal Register**.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 6, 2013. FDA has verified the applicant's claims that the NDA for ZYDELIG (NDA 206545) was initially submitted on December 6, 2013.

3. *The date the application was approved:* July 23, 2014. FDA has verified the applicant's claims that NDA 206545 was approved on July 23, 2014.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 494 days or 708 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03701 Filed 2–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0478]

Sebela Ireland, Ltd. et al.; Withdrawal of Approval of 24 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 24 abbreviated

new drug applications (ANDAs) from multiple applicants. The holders of the applications 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 March 26, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications 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 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 040398	MiCort-HC (hydrocortisone acetate) Cream USP, 2%	Sebela Ireland, Ltd., c/o Sebela Pharmaceuticals, Inc., 645 Hembree Parkway, Suite 1, Roswell, GA 30076.
ANDA 071893	Acetohexamide Tablets, 250 milligrams (mg)	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 071894	Acetohexamide Tablets, 500 mg	Do.
ANDA 073143	Cyclobenzaprine Hydrochloride (HCl) Tablets USP, 10 mg	Do.
ANDA 074576	Captopril Tablets USP, 12.5 mg, 25 mg, 50 mg, and 100 mg	Do.
ANDA 076607	Quinapril Tablets USP, Equivalent to (EQ) 5 mg base, EQ 10 mg base, EQ 20 mg base, and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 076786	Donepezil HCl Tablets USP, 5 mg and 10 mg	Do.
ANDA 077483	Benazepril HCl and Hydrochlorothiazide Tablets, 5 mg/6.25 mg, 10 mg/12.5 mg, 20 mg/12.5 mg, and 20 mg/25 mg.	Do.
ANDA 078502	Eliphos (calcium acetate) Tablets USP, 667 mg	Cypress Pharmaceutical, Inc., 10 North Park Pl., Suite 201, Morristown, NJ 07960.
ANDA 081019	Chlorzoxazone Tablets USP, 500 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083821	Brompheniramine Maleate Injection, 10 mg/milliliter (mL)	Do.
ANDA 084408	Bethanechol Chloride Tablets USP, 10 mg	Do.
ANDA 084441	Bethanechol Chloride Tablets USP, 25 mg	Do.
ANDA 085283	Theolair (theophylline) Tablets, 125 mg and 250 mg	3M Drug Delivery Systems, 3M Center, Bldg. 275–3E–02, 2510 Conway Ave., St. Paul, MN 55144.
ANDA 085738	Betamethasone Sodium Phosphate Injection, EQ 3 mg base/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087444	Bethanechol Chloride Tablets USP, 50 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 087792	Fluorouracil Injection USP, 50 mg/mL	Spectrum Pharmaceuticals, Inc., 157 Technology Dr., Irvine, CA 92618.
ANDA 087978	Diphenhydramine HCl Capsules, 50 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788.
ANDA 090417	Carbinoxamine Maleate Tablets USP, 4 mg	Cypress Pharmaceutical, Inc.
ANDA 090418	Carbinoxamine Maleate Oral Solution, 4 mg/5 mL	Do.
ANDA 090468	Zyfrel (acetaminophen and hydrocodone bitartrate) Oral Solution, 325 mg/7.5 mg per 15 mL.	Do.
ANDA 091034	Dorzolamide HCl Ophthalmic Solution USP, EQ 2% base	Zambon S.p.A., c/o Camargo Pharmaceutical Services, LLC, 9825 Kenwood Rd., Suite 203, Cincinnati, OH 45242.
ANDA 200794	Pantoprazole Sodium Delayed-Release Tablets USP, EQ 20 mg base and EQ 40 mg base.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc.
ANDA 206438	Hydrocodone Bitartrate and Chlorpheniramine Maleate Oral Solution, 5 mg/4 mg per 5 mL.	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 26, 2018. 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 March 26, 2018 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: February 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03700 Filed 2–22–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on