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 biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product IMFINZI (durvalumab). IMFINZI is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. Subsequent to this approval, the USPTO received a patent term restoration application for IMFINZI (U.S. Patent Nos. 8,779,108 and 9,493,565) from MedImmune Limited, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated, January 9, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of IMFINZI 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 IMFINZI is 1,755 days. Of this time, 1,554 days occurred during the testing phase of the regulatory review period, while 201 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 (21 U.S.C. 355(i)) became effective:* July 13, 2012. FDA has verified the applicant's claim that the date the initial investigational new drug application became effective was on July 13, 2012.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 13, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for IMFINZI (BLA 761069) was initially submitted on October 13, 2016.

3. *The date the application was approved:* May 1, 2017. FDA has verified the applicant's claim that BLA 761069 was approved on May 1, 2017.

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 application for patent extension, this applicant seeks 159 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: October 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22806 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3761]

Sanofi-Aventis, U.S., LLC, et al.; Withdrawal of Approval of 20 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 20 new drug applications (NDAs) 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 November 19, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

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
NDA 006002	Aralen Hydrochloride (chloroquine hydrochloride (HCl)) Injection, Equivalent to (EQ) 40 milligram (mg) base/milliliter (mL); Aralen (chloroquine phosphate) Tablets, EQ 300 mg base.	Sanofi-Aventis, U.S., LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 008107	Leucovorin calcium for Injection USP, EQ 60 mg base/vial for solution, oral; EQ 3 mg base/mL injection; EQ 50 mg base/vial injection; EQ 100 mg base/vial injection; EQ 350 mg base/vial injection.	Hospira Inc., Subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 009321	Cholografin Meglumine (iodipamide meglumine) Injection, 10.3% and 52% (cholografin sodium, 20%).	Bracco Diagnostics, Inc., 259 Prospect Plains Rd., Monroe Township, NJ 08831.
NDA 017566	Brevicon (ethinyl estradiol; norethindrone) Tablets, 0.035 mg/0.5 mg (21-Day Regimen).	Allergan Pharmaceuticals International, Ltd., c/o Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
NDA 018181	Mycelex (clotrimazole) Topical Solution, 1%	Bayer HealthCare LLC, 100 Bayer Blvd., 100 Bayer Rd., Pittsburgh, PA 15205.
NDA 018182	Mycelex-7 (clotrimazole) Tablets, 100 mg	Do.
NDA 018183	Mycelex (clotrimazole) Topical Cream, 1%	Do.
NDA 018230	Mycelex-7 (clotrimazole) Topical Vaginal Cream, 1%.	Do.
NDA 018856	D-Xylose (xylose) Powder, 25 grams (g)/bottle ...	Lyne Laboratories, 10 Burke Dr., Brockton, MA 02301.
NDA 018874	Calcijex (calcitriol) Injection, 0.001 mg/mL and 0.002 mg/mL.	AbbVie, Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 020214	Zemuron (rocronium bromide) Injection, 50 mg/5 mL (10 mg/mL); 10 mg/mL (10 mg/mL); 100 mg/10 mL (10 mg/mL).	Organon USA Inc., Subsidiary of Merck & Co., Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020389	Mycelex-7 Combination Pack (clotrimazole) Topical Vaginal Cream and Tablets, 1%, 100 mg.	Bayer HealthCare LLC.
NDA 020528	Mavik (trandolapril) Tablets, 1 mg, 2 mg, and 4 mg.	AbbVie, Inc.
NDA 020738	Teveten (eprosartan mesylate) Tablets, 300 mg, 400 mg, and 600 mg.	Do.
NDA 020863	Pletal (cilostazol) Tablets, 50 mg and 100 mg	Otsuka Pharmaceutical Development and Commercialization, Subsidiary of Otsuka Pharmaceutical Company, Ltd., 2440 Research Blvd., Rockville, MD 20850.
NDA 021268	Teveten HCT (eprosartan mesylate and hydrochlorothiazide) Tablets, 600/12.5 mg and 600/25 mg.	AbbVie, Inc.
NDA 021410	Avandamet (rosiglitazone maleate and metformin hydrochloride (HCl)) Tablets, 500 mg EQ 1 mg base; 500 mg EQ 2 mg base; 500 mg EQ 4 mg base; 1 g EQ 2 mg base; 1 g EQ 4 mg base.	GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 021511	Copegus (ribavirin) Tablets, 200 mg and 400 mg	Hoffmann La-Roche, Inc., Subsidiary of Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080.
NDA 021700	Avandaryl (glimepiride and rosiglitazone maleate) Tablets, 1 mg/4 mg; 2 mg/4 mg; 2 mg/8 mg; 4 mg/4 mg; 4 mg/8 mg.	SB Pharmco Puerto Rico Inc., Subsidiary of GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 205123	Olysio (simeprevir sodium) Capsules, EQ 150 mg base.	Janssen Pharmaceuticals, Inc., 1000 U.S. Rte. 202 South, Raritan, NJ 08869.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 19, 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 November 19, 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: October 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22805 Filed 10–18–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute 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: National Heart, Lung, and Blood Institute Special Emphasis Panel;