TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
HCP Screener	1,233	1	1,233	.08 (5 minutes)	98.64
Consumer Study	493	1	493	.33 (20 minutes)	162.69
HCP Study	493	1	493	.33 (20 minutes)	162.69
Total					522.66

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

References

The following references are on display with the Dockets Management Staff, HFA–305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Krosnick, J.A. and S. Presser, ''Question and Questionnaire Design.'' In P.V. Marsden and J.D. Wright (Eds.). *Handbook of Survey Research* (2nd Ed.). Emerald: Bingley, UK, 2010.
2. Fishbein, M. and I. Ajzen, *Predicting and Changing Behavior: The Reasoned Action Approach*. New York, NY: Psychology Press, 2010.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05330 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–0340]

Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by May 17, 2021. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 13, 2021. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–E–0340 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the 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, 240–402–7500.

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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM. HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis, or arthritis secondary to inflammatory disease (*e.g.,* rheumatoid arthritis, hemochromatosis, etc.). The device system is for prescription use. Subsequent to this approval, the USPTO received a patent term restoration application for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM (U.S. Patent No. 6,409,767) from European Foot Platform, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM 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 HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM is 4,676 days. Of this time, 3,661 days occurred during the testing phase of the regulatory review period, while 1,015 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device:* August 17, 2006. FDA has verified the applicant's claim that the date on which the device is first used with human subjects as part of a clinical investigation to be filed with FDA to secure premarket approval of the device was August 17, 2006.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 24, 2016. FDA has verified the applicant's claim that the premarket approval application (PMA) for HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM (PMA 160036) was initially submitted August 24, 2016.

3. *The date the application was approved:* June 4, 2019. FDA has verified the applicant's claim that PMA 160036 was approved on June 4, 2019.

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 1,825 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: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05371 Filed 3–15–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0212]

Bristol-Meyers Squibb Company, et al.; Withdrawal of Approval of 19 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 19 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 April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@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 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 009218	Coumadin (warfarin sodium) Tablets, 1 milligram (mg), 2 mg, 2.5 mg, 3 mg, 4 mg, 5 mg, 6 mg, 7.5 mg, and 10 mg. Coumadin (warfarin sodium) Injection, 5 mg/vial, 50 mg/vial, and 75 mg/vial.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
NDA 011664	Decadron (dexamethasone) Tablets, 0.25 mg, 0.5 mg, 0.75 mg, 1.5 mg, 4 mg, and 6 mg.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., 1 Merck Dr., Whitehouse Station, NJ 08889.
NDA 017481	Vermox (mebendazole) Chewable Tablets, 100 mg	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 018538	Lozol (indapamide) Tablets, 1.25 mg, and 2.5 mg	Sanofi-aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 018986	Pralidoxime Chloride Injection (auto-injector), 600 mg/2 milliliters (mL) (300 mg/mL).	Meridian Medical Technologies, Inc., 1945 Craig Rd., St. Louis, MO 63146.
NDA 019999	Morphine Sulfate Injection (auto-injector), 10 mg/0.7 mL	Do.
NDA 020363	Famvir (famciclovir) Tablets, 125 mg, 250 mg, and 500 mg ...	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936–1080.
NDA 020711	Zyban (bupropion hydrochloride (HCl)) Extended-Release Tablets, 100 mg, and 150 mg.	GlaxoSmithKline LLC, 5 Crescent Dr., Philadelphia, PA 19112.
NDA 020809	Diclofenac Sodium Ophthalmic Solution, 0.1%	Alcon Research, LLC, 6201 South Freeway, Fort Worth, TX 76134.
NDA 021713	Abilify (aripiprazole) Oral Solution, 1 mg/mL	Otsuka Pharmaceutical Co., Ltd. c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850.
NDA 021729	Abilify (aripiprazole) Discmelt Orally Disintegrating Tablets, 10 mg, 15 mg, 20 mg, and 30 mg.	Do.
NDA 021866	Abilify (aripiprazole) Injection, 9.75 mg/1.3 mL (7.5 mg/mL) ...	Do.
NDA 022024	Actoplus Met XR (metformin HCl and pioglitazone) Extended-Release Tablets, 1gram (g)/Equivalent to (EQ) 15 mg base and 1 g/EQ 30 mg base.	Takeda Pharmaceutical U.S.A. Inc., 95 Hayden Ave., Lexington, MA 02421.
NDA 050605	Ceftin (cefuroxime axetil) Tablets, EQ 125 mg base, EQ 250 mg base, and EQ 500 mg base.	GlaxoSmithKline Intellectual Property (no. 2) Ltd. England, c/o GlaxoSmithKline, 1250 South Collegeville Rd., Collegeville, PA 19426.
NDA 050672	Ceftin (cefuroxime axetil) Oral Suspension, EQ 125 mg base/5 mL and EQ 250 mg base/5 mL.	Do.
NDA 207988	Zurampic (lesinurad) Tablets, 200mg	Ironwood Pharmaceuticals, Inc., 100 Summer St., Suite 2300, Boston MA 02110.
NDA 208383	Bevyxxa (betrixaban) Capsules, 40 mg and 80 mg	Portola Pharmaceuticals, Inc., 270 East Grand Ave., South San Francisco, CA 94080.
NDA 210709	Tekturna (aliskiren hemifumarate) Capsules (Pellets), EQ 37.5 mg base.	Nodem Pharma DAC, 4820 Emperor Blvd., Durham, NC 27703.
NDA 210874	Qternmet XR (dapagliflozin, metformin HCl and saxagliptin) Extended-Release Tablets, 2.5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 2.5 mg base, 5 mg/1 g/EQ 5 mg base, and 10 mg/1 g/EQ 5 mg base.	AstraZeneca AB, c/o AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 15, 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