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 or biologic 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 SPINRAZA (nusinersen sodium). SPINRAZA is indicated for the treatment of spinal muscular atrophy in pediatric and adult patients. Subsequent to this approval, the USPTO received patent term restoration applications for SPINRAZA (U.S. Patent Nos. 7,838,657 and 8,110,560 from University of Massachusetts, and U.S. Patent Nos. 8,361,977 and 8,980,853 from Biogen MA Inc., and Cold Spring Harbor Laboratory), and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 8, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SPINRAZA 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 SPINRAZA is 1,891 days. Of this time, 1,799 days occurred during the testing phase of the regulatory review period, while 92 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* October 22, 2011. FDA has verified the applicants' claims that the date the investigational new drug application became effective was on October 22, 2011.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* September 23, 2016. FDA has verified the applicants' claims that the new drug application (NDA) for SPINRAZA (NDA 209531) was initially submitted on September 23, 2016.

3. *The date the application was approved:* December 23, 2016. FDA has verified the applicants' claims that NDA 209531 was approved on December 23, 2016.

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, these applicants seek 29 days, 210 days, 937 days, or 992 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 26, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23719 Filed 10–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–1031]

Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' This draft guidance addresses the process through which registrants of drug establishments should submit to FDA reports on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution, as required by the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Submit either electronic or written comments on the draft guidance by January 3, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2021–D–1031 for ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' Received comments 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993–0002; or Policy and Regulations Staff, HFV–6, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Neil Stiber, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4128, Silver Spring, MD 20993–0002, 301–796–8944; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; Neal Bataller, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, (HFV–210), Rm. 2612, Rockville, MD 20855, 240–402–5745.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was enacted to aid response efforts and ease the economic impact of the Coronavirus Disease 2019 (COVID–19). In addition, the CARES Act included authorities to enhance FDA's ability to identify, prevent, and mitigate possible drug shortages by, among other things, improving FDA's visibility into drug supply chains. Section 3112(e) of the CARES Act (Pub. L. 116–136) added section 510(j)(3) of the FD&C Act (21 U.S.C. 360(j)(3)) to require that each person (including repackers and relabelers) who registers with FDA under section 510 of the FD&C Act with regard to a drug must report annually to FDA the amount of each listed drug that was manufactured, prepared, propagated, compounded, or processed by such person for commercial distribution.

This draft guidance is intended to assist registrants of drug establishments in submitting to FDA reports on the amount of each listed drug manufactured, prepared, propagated, compounded, or processed for commercial distribution, as required by section 510(j)(3) of the FD&C Act. The draft guidance addresses the content of reports, the timing of reports, and the process for report submission.

This draft guidance describes the process that should be used for reporting by each person who registers with FDA under section 510 of the FD&C Act with regard to a listed drug (including a finished dosage form product, an active pharmaceutical ingredient, and other listed drugs), except for biological products or categories thereof exempted by an order under section 510(j)(3)(B)). The process described in this guidance applies to such reporting with respect to listed drugs, including medical gases, homeopathic products, products

marketed in accordance with requirements under section 505G of the FD&C Act (21 U.S.C. 355h), often referred to as over-the-counter monograph drugs, and animal drug products that are not approved, conditionally approved, or indexed under sections 512, 571, and 572 of the FD&C Act (21 U.S.C. 360b, 360ccc, and 360ccc–1).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA.

The regulatory citations and associated collections of information that OMB approved are as follows:

- Registrants who own or operate a domestic or foreign establishment that manufactures, prepares, propagates, compounds, or processes a drug must submit to FDA information on the amount of listed drugs that they manufacture, prepare, propagate, compound, or process. Registrants must submit information on the following listed drugs: (1) Finished dosage form products, (2) drug products with active pharmaceutical ingredients, and (3) other listed drugs. The collection of information under section 510(j)(3) of the FD&C Act (as added by section 3112 of the CARES Act) on the amount of listed drug products has been approved under OMB control number 0910–0045. FDA is developing an electronic portal for registrants to submit this information.
- FDA requires that applicants submit annual reports for abbreviated new drug applications, biologics license applications, and new drug applications. The collections of information in parts 314 and 601 have been approved under OMB control numbers 0910–0001 and 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 27, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23722 Filed 10–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1071]

Allergan Sales, LLC, et al.; Withdrawal of Approval of 18 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 18 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 December 1, 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.

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 007409	Bentyl (dicyclomine hydrochloride (HCl)) Capsules, 10 milligram (mg). Bentyl (dicyclomine HCl) Tablets, 20 mg.	Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940.
NDA 013625	Norinyl 1 + 50 (norethindrone and mestranol) Tablets, 0.05 mg/1 mg. Norinyl (norethindrone and mestranol) Tablets, 0.1 mg/2 mg	Actavis Laboratories UT, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 145 Brandywine Pkwy., West Chester, PA 19380.
NDA 014169	Dendrid (idoxuridine) Ophthalmic Solution, 0.1%	Alcon Laboratories, Inc., 6201 South Freeway, Fort Worth, TX 76134.
NDA 019404	Ocufen (flurbiprofen sodium) Ophthalmic Solution, 0.03%	Allergan, Inc., 2525 Dupont Dr., Irvine, CA 92612.
NDA 019784	Ibuprofen Oral Suspension, 100 mg/5 milliliters (mL)	Abbott Laboratories Established Pharmaceuticals Products Division, 200 Abbott Park Rd., Abbott Park, IL 60064.
NDA 020010	Lotrisone (betamethasone dipropionate and clotrimazole) Lotion, Equivalent to (EQ) 0.05% base/1%.	Merck Sharp and Dohme Corp., a subsidiary of Merck and Co., Inc., 1 Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 020098	Mivacron (mivacurium chloride) Solution, EQ 2 mg base/mL, EQ 10 mg base/5 mL, and EQ 20 mg base/10 mL. Mivacron in Dextrose 5% in plastic container (mivacurium chloride) Injectable, EQ 0.5 mg base/mL and EQ 50 mg base/100 mL.	AbbVie, Inc., 1 N Waukegan Rd., North Chicago, IL 60064
NDA 020412	Zerit (stavudine) Capsules, 5 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.