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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Reporting Amount of Listed Drugs and Biological Products Under Section 510(j)(3) of the FD&C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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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.

Application No.	Drug	Applicant
NDA 020509	Gemzar (gemcitabine HCl) Injection, EQ 200 mg base and EQ 1 gram (g) base.	Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285.
NDA 020696	Antizol (fomepizole) Injection, 1.5 g/1.5 mL	Par Sterile Products, LLC, 6 Ram Ridge Rd., Chestnut Ridge, NY 10977.
NDA 020705	Rescriptor (delavirdine mesylate) Tablets, 100 mg and 200 mg.	ViiV Healthcare Co., 5 Moore Dr., Research Triangle Park, NC 27709.
NDA 021114	Betaxon (levobetaxolol HCl) Ophthalmic Suspension, EQ 0.5% base.	Alcon Laboratories, Inc.
NDA 021199	Quixin (levofloxacin) Ophthalmic Solution, 0.5%	Santen Inc., 6401 Hollis St., Suite 125, Emeryville, CA 94608.
NDA 021571	Iquix (levofloxacin) Ophthalmic Solution, 1.5%	Do.
NDA 050704	DaunoXome (daunorubicin citrate liposome injection), EQ 2 mg base/mL.	Galen Limited, 25 Fretz Rd., Souderton, PA 18964.
NDA 204736	AcipHex Sprinkle (rabeprazole sodium) Delayed Release Capsules, 5 mg and 10 mg.	Aytu BioScience Inc., 373 Inverness Parkway, Suite 206, Englewood, CO 80112.
NDA 205060	Epanova (omega-3-carboxylic acids) Capsules, 1 gram (1 g contains at least 850 mg of polyunsaturated fatty acids).	AstraZeneca Pharmaceuticals LP, 1800 Concord Pike, Wilmington, DE 19803.
NDA 206843	Daklinza (daclatasvir dihydrochloride) Tablets, EQ 30 mg base, EQ 60 mg base, and EQ 90 mg base.	Bristol-Myers Squibb Co.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of December 1, 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 December 1, 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: October 25, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23729 Filed 10–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1817; FDA–2020–E–1818; FDA–2020–E–1820]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU

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 ENHERTU and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

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 January 3, 2022. 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 May 2, 2022. 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 January 3, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 2022. 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 Nos. FDA–2020–E–1817; FDA–2020–E–1818; and FDA–2020–E–1820, for ''Determination of Regulatory Review Period for Purposes of Patent Extension; ENHERTU.'' Received comments, those filed in a timely manner (see