

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

**Reporting Associated With Designated New Animal Drugs for Minor Use and Minor Species—21 CFR Part 516**

*OMB Control Number 0910–0605—Extension*

The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to implement regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species as well as uncommon diseases in major animal species (21 U.S.C. 360ccc). This statutory authority provides incentives designed to help pharmaceutical companies overcome the financial burdens they face in providing limited-demand animal drugs. These incentives are only available to sponsors who have had their drugs designated by FDA under section 573 of the MUMS Act. Minor use drugs are drugs for use in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) that are needed for diseases that occur in only a small number of animals either because they occur infrequently or in limited geographic areas. Minor species are all animals other than the major species, for example, zoo animals,

ornamental fish, parrots, ferrets, and guinea pigs. Some animals of agricultural importance are also minor species. These include animals such as sheep, goats, catfish, and honeybees.

MUMS-drug designation is completely optional for drug sponsors. The associated reporting only applies to those sponsors who request and are subsequently granted MUMS-drug designation status. Our regulations in 21 CFR part 516 specify the criteria and procedures for requesting MUMS-drug designation as well as the annual reporting requirements for MUMS designees. Sponsors use FDA’s “eSubmitter” system to fill out a series of system generated screens to submit their request and annual report electronically. To access the “eSubmitter” system, sponsors will use a previously established account. Additional information about this system is available on our website at: <https://www.fda.gov/industry/fda-esubmitter>.

*Description of Respondents:* The respondents to this information collection are pharmaceutical companies that sponsor new animal drugs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

| 21 CFR section; activity                                                              | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---------------------------------------------------------------------------------------|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| 516.20; content and format of MUMS-drug designation request .....                     | 15                    | 5                                  | 75                     | 16                          | 1,200       |
| 516.26; requirements for amending MUMS-drug designation .....                         | 3                     | 1                                  | 3                      | 2                           | 6           |
| 516.27; change in sponsorship of MUMS-drug designation .....                          | 1                     | 1                                  | 1                      | 1                           | 1           |
| 516.29; termination of MUMS-drug designation .....                                    | 2                     | 1                                  | 2                      | 1                           | 2           |
| 516.30; requirements of annual reports from sponsor(s) of MUMS-designated drugs ..... | 15                    | 5                                  | 75                     | 2                           | 150         |
| 516.36; consequences for insufficient quantities of MUMS-designated drugs .....       | 1                     | 1                                  | 1                      | 3                           | 3           |
| Total .....                                                                           |                       |                                    |                        |                             | 1,362       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 19, 2022.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
[FR Doc. 2022–16387 Filed 7–29–22; 8:45 am]  
**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
[Docket No. FDA–2022–N–1528]  
**Lupin Pharmaceuticals, Inc., et al.; Withdrawal of Approval of Seven 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 seven abbreviated new drug applications (ANDAs) 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 August 31, 2022.

**FOR FURTHER INFORMATION CONTACT:** Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, [Martha.Nguyen@fda.hhs.gov](mailto:Martha.Nguyen@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 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                                                                                               |
|------------------|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| ANDA 065125 .... | Ceftriaxone for Injection, Equivalent to (EQ) 250 milligrams (mg) base/vial; EQ 500 mg base/vial; EQ 1 gram (g) base/vial; EQ 2 g base/vial. | Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202. |
| ANDA 078188 .... | Irinotecan Hydrochloride Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL).                                          | Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.                                    |
| ANDA 090088 .... | Anastrozole Tablets, 1 mg .....                                                                                                              | Do.                                                                                                     |
| ANDA 206002 .... | Bosentan Tablets, 62.5 mg and 125 mg .....                                                                                                   | Alvogen Pine Brook, LLC, 44 Whippany Rd., Suite 300, Morristown, NJ 07960.                              |
| ANDA 212185 .... | Chlorzoxazone Tablets, 375 mg and 750 mg .....                                                                                               | Glenmark Pharmaceuticals Inc., USA, 750 Corporate Dr., Mahwah, NJ 07430.                                |
| ANDA 212186 .... | Amphetamine Sulfate Tablets, 5 mg and 10 mg .....                                                                                            | Do.                                                                                                     |
| ANDA 213132 .... | Arformoterol Tartrate Inhalation Solution, EQ 0.015 mg base/2 mL.                                                                            | Do.                                                                                                     |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 31, 2022. 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 August 31, 2022 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: July 25, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-16383 Filed 7-29-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket Nos. FDA-2020-E-1588; FDA-2020-E-1591; and FDA-2020-E-1592]

### Determination of Regulatory Review Period for Purposes of Patent Extension; REBLOZYL

**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 REBLOZYL 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 September 30, 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 January 30, 2023. 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 September 30, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 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.”