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 LYMPHOSEEK (technetium (Tc 99m) tilmanocept). LYMPHOSEEK is indicated for lymphatic mapping with a hand-held gamma counter to assist in the localization of lymph nodes draining a primary tumor site in patients with breast cancer or melanoma. Subsequent to this approval, the USPTO received a patent term restoration application for LYMPHOSEEK (U.S. Patent No. 6,409,990) from Navidea Biopharmaceuticals, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 4, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of LYMPHOSEEK 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 LYMPHOSEEK is 4,398 days. Of this time, 3,816 days occurred during the testing phase of the regulatory review period, while 582 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* February 28, 2001. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on February 28, 2001.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 10, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for LYMPHOSEEK (NDA 202207) was initially submitted on August 10, 2011.

3. *The date the application was approved:* March 13, 2013. FDA has verified the applicant's claim that NDA 202207 was approved on March 13, 2013.

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 1,826 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: February 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03610 Filed 2–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0341]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements of our regulations concerning new animal drugs for investigational use.

DATES: Submit either electronic or written comments on the collection of information by April 23, 2018.

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 April 23, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 23, 2018. 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–2018–N–0341 for ''New Animal Drugs for Investigational Use.'' 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.

- 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.gpo.gov/fdsys/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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests 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.

New Animal Drugs for Investigational Use—21 CFR Part 511

OMB Control Number 0910–0117—Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to approve new animal drugs. A new animal drug application (NADA) cannot be approved until, among other things, the new animal drug has been demonstrated to be safe and effective for its intended use(s). In order to properly test a new animal drug for an intended use, appropriate scientific investigations must be conducted. Under specific circumstances, section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) permits the use of an investigational new animal drug to generate data to support an NADA approval. Section 512(j) of the FD&C Act authorizes us to issue regulations relating to the investigational use of new animal drugs.

Our regulations in part 511 (21 CFR part 511) set forth the conditions for investigational use of new animal drugs and require reporting and recordkeeping. The information collected is necessary to protect the public health. We use the information to determine that investigational animal drugs are distributed only to qualified investigators, adequate drug accountability records are maintained, and edible food products from treated food-producing animals are safe for human consumption. We also use the information collected to monitor the validity of the studies submitted to us to support new animal drug approval.

Reporting: Our regulations require that certain information be submitted to us in a ''Notice of Claimed Investigational Exemption for a New Animal Drug'' (NCIE) to qualify for the exemption and to control shipment of the new animal drug and prevent potential abuse. The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6) information regarding the use of edible tissues from investigational animals (§ 511.1(b)(4) (21 CFR 511.1(b)(4)). If the new animal drug is to be used in food-producing animals, *e.g.,* cattle, swine, chickens, fish, etc., certain data must be submitted to us to obtain authorization for the use of edible food products from treated food-producing animals (§ 511.1(b)(5)). We require sponsors upon request to submit information with respect to the investigation to determine whether there are grounds for terminating the exemption (§ 511.1(b)(6)). We require sponsors to report findings that may suggest significant hazards pertinent to the safety of the new animal drug (§ 511.1(b)(8)(ii)). We also require

reporting by importers of investigational new animal drugs for clinical investigational use in animals (§ 511.1(b)(9)). The information provided by the sponsor in the NCIE is needed to ensure that the proposed investigational use of the new animal drug is safe and that any edible food will not be distributed without proper authorization from FDA. Information contained in an NCIE submission is monitored under our Bio-Research Monitoring Program. This program permits us to monitor the validity of the studies and to ensure the proper use of the drugs is maintained by the investigators.

Recordkeeping: If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery (§ 511.1(a)(3) and (b)(3)). We require complete records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug (§ 511.1(b)(7)). We also require records of all reports received by a sponsor from investigators to be retained for 2 years after the termination of an investigational exemption or approval of a new animal drug application (§ 511.1(b)(8)(i)).

Description of Respondents: Respondents to this collection of information are persons who use new animal drugs for investigational purposes. Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities, as well as research firms and members of the medical professions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4); submission of NCIE	104	15.38	1,600	1	1,600
511.1(b)(5); submission of data to obtain authorization for the use of edible food products	104	0.30	31	8	248
511.1(b)(6); submission of any additional information upon request of FDA	104	0.02	2	1	2
511.1(b)(8)(ii); reporting of findings that may suggest significant hazards pertinent to the safety of the new animal drug	104	0.14	15	2	30
511.1(b)(9); reporting by importers of investigational new animal drugs for clinical investigational use in animals	104	0.14	15	8	120
Total			1,663		2,000

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section/activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery	104	2.5	260	1	260
511.1(b)(3); maintain records showing the name and post office address of the expert or expert organization to whom the new animal drug or feed containing same is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery	104	15.38	1,600	1	1,600
511.1(b)(7); maintain records of the investigation, including records of the receipt and disposition of each shipment or delivery of the investigational new animal drug	104	15.38	1,600	3.5	5,600
511.1(b)(8)(i); maintain records of all reports received by a sponsor from investigators	104	15.38	1,600	3.5	5,600
Total			5,060		13,060

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on our informal communication with industry. Based on the number of sponsors subject to animal drug user fees, we estimate that there are 104 respondents. We use this estimate consistently throughout the table and calculate the ''number of responses per respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours

(*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, etc.) is derived from our records. The burden for this information collection has changed since the last OMB approval. We estimate an overall increase in burden that we attribute to an increase in the number of annual responses and records.

Dated: February 15, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03609 Filed 2–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0508]

Parke-Davis, Subsidiary of Pfizer, Inc. et al.; Withdraw of Approval of 38 New Drug Applications and 43 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 38 new drug applications (NDAs) and 43 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications 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 March 26, 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 holders of the applications 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.

TABLE 1

Application No.	Drug	Applicant
NDA 010151	Dilantin (phenytoin sodium) Injection USP, 50 milligrams (mg)/milliliter (mL).	Parke-Davis, Subsidiary of Pfizer, Inc., 235 East 42nd St., New York, NY 10017.
NDA 011903	Zolyse (chymotrypsin) for Ophthalmic Solution, 750 units/vial	Alcon Laboratories, Inc., 6201 S. Freeway, TC–45, Fort Worth, TX 76134–2099.
NDA 012125	Carbocaine (mepivacaine hydrochloride (HCl)) Injection USP, 3%.	Hospira Inc., 8401 W. 102nd St., Pleasant Prairie, WI 53158.
	Carbocaine with Neo-Cobefrin (mepivacaine HCl; levonordefrin) Injection USP, 2%; 0.05 mg/mL.	
NDA 012516	Sansert (methysergide maleate) Tablets, 2 mg	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936–1080.
NDA 016774	Serentil (mesoridazine besylate) Tablets, Equivalent to (EQ) 10 mg base, 25 mg base, 50 mg base, and 100 mg base.	Do.
NDA 016775	Serentil (mesoridazine besylate) Injection, EQ 25 mg base/mL.	Do.
NDA 016793	Cytosar-U (cytarabine) for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram (g)/vial, and 2 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 016997	Serentil (mesoridazine besylate) Oral Concentrate, EQ 25 mg base/mL.	Novartis Pharmaceuticals Corp.
NDA 017364	Aquatensen (methyclothiazide) Tablets USP, 5 mg	Meda Pharmaceuticals, Inc., 265 Davidson Ave., Suite 400, Somerset, NJ 08873.
NDA 017575	DTIC-Dome (dacarbazine) for Injection, 100 mg/vial and 200 mg/vial.	Bayer Healthcare Pharmaceuticals, Inc., 100 Bayer Blvd., Whippany, NJ 07981.
NDA 017717	Gyne-Lotrimin (clotrimazole) Vaginal Tablets, 100 mg	Bayer HealthCare, LLC, 100 Bayer Blvd., P.O. Box 915, Whippany, NJ 07981–0915.
NDA 017869	Funduscein-25 (fluorescein sodium) Injection, 25%	Novartis Pharmaceuticals Corp.
NDA 017993	Hydergine (ergoloid mesylates) Tablets, 0.5 mg and 1 mg	Do.
NDA 018052	Gyne-Lotrimin (clotrimazole) Vaginal Cream, 1%	Bayer HealthCare, LLC.
NDA 018128	Ovcon-50 (norethindrone and ethinyl estradiol) Tablets USP (21-Day Regimen), 1 mg and 0.05 mg.	Warner Chilcott Co., LLC, c/o Warner Chilcott (US), LLC, 100 Enterprise Dr., Rockaway, NJ 07866.
NDA 018397	Chlor-Trimeton (chlorpheniramine maleate and pseudoephedrine sulfate) Extended-Release Tablets, 8 mg and 120 mg.	Bayer HealthCare, LLC.
NDA 018418	Hydergine (ergoloid mesylates) Oral Solution, 1 mg/mL	Novartis Pharmaceuticals Corp.
NDA 018439	Multi-Vitamins Concentrate for Infusion, Injection	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 018471	Ocuclear (oxymetazoline HCl) Ophthalmic Solution, 0.025%	Bayer HealthCare, LLC.
NDA 018517	Metronidazole Tablets USP, 250 mg and 500 mg	IVAX Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 018969	Liposyn III 10% (soybean oil) Injection, 10%	Hospira, Inc.
NDA 020045	Shade UVAGuard (avobenzone, octinoxate, oxybenzone) Lotion, 3%/7.5%/3%.	Bayer HealthCare, LLC.
NDA 020289	Gyne-Lotrimin Combination Pack (clotrimazole) Vaginal Cream and Vaginal Tablets, 1% and 100 mg.	Do.