Application No.	Drug	Applicant
ANDA 072420	Amoxapine Tablets, 100 mg	Do.
ANDA 072421	Amoxapine Tablets, 150 mg	Do.
ANDA 072609	Prazosin HCl Capsules, EQ 5 mg base	Do.
ANDA 072751	Verapamil HCl Tablets, 40 mg	PLIVA Inc.
ANDA 072923	Verapamil HCl Tablets, 40 mg	Watson Laboratories, Inc.
ANDA 072953	Oxazepam Capsules, 15 mg	Do.
ANDA 072954	Oxazepam Capsules, 30 mg	Do.
ANDA 073093	Baclofen Tablets, 20 mg	Do.
ANDA 073122	Loperamide HCl Capsules, 2 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073334	Amiloride HCl and Hydrochlorothiazide Tablets, EQ 5 mg anhydrous; 50 mg.	Watson Laboratories, Inc.
ANDA 073352	Atenolol Tablets, 50 mg	Do.
ANDA 073353	Atenolol Tablets, 100 mg	Do.
ANDA 073637	Piroxicam Capsules, 10 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073638	Piroxicam Capsules, 20 mg	Do.
ANDA 074026	Triamterene and Hydrochlorothiazide Tablets, 25 mg and 37.5 mg.	PLIVA Inc.
ANDA 074359	Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules, 325 mg, 50 mg, 40 mg, and 30 mg.	Watson Laboratories, Inc.
ANDA 074405	Flurbiprofen Tablets, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074421	Cyclobenzaprine HCl Tablets, 10 mg	PLIVA Inc.
ANDA 074436	Cyclobenzaprine HCl Tablets, 10 mg	Watson Laboratories, Inc.
ANDA 074442	Gemfibrozil Tablets, 600 mg	Do.
ANDA 074479	Alprazolam Tablets, 0.25 mg, 0.5 mg, and 1 mg	Do.
ANDA 074647	Flurbiprofen Tablets, 50 mg and 100 mg	PLIVA Inc.
ANDA 074762	Guanfacine HCl Tablets, EQ 1 mg base and EQ 2 mg base	Watson Laboratories, Inc.
ANDA 074836	Acyclovir Tablets, 400 mg and 800 mg	IVAX Pharmaceuticals, Inc.
ANDA 074892	Etodolac Tablets, 400 mg and 500 mg	Watson Laboratories, Inc.
ANDA 074955	Ketorolac Tromethamine Tablets, 10 mg	Do.
ANDA 074964	Clonazepam Tablets, 0.5 mg, 1 mg, and 2 mg	Do.
ANDA 075067	Cromolyn Sodium Inhalation Solution, 10 mg/mL	Actavis Mid Atlantic LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 075069	Etodolac Tablets, 400 mg	Watson Laboratories, Inc.
ANDA 075262	Albuterol Sulfate Syrup, EQ 2 mg base/5 mL	Actavis Mid Atlantic LLC.
ANDA 075284	Ketorolac Tromethamine Tablets, 10 mg	PLIVA Inc.
ANDA 081165	Hydroxyzine Pamoate Capsules, EQ 25 mg HCl	Watson Laboratories, Inc.
ANDA 084503	Hydralazine HCl Tablets, 50 mg	Do.
ANDA 085054	Hydrochlorothiazide Tablets, 25 mg	Actavis Mid Atlantic LLC.
ANDA 085084	Prednisone Tablets, 5 mg	Watson Laboratories, Inc.
ANDA 085085	Prednisolone Tablets, 5 mg	Do.
ANDA 085208	Hydrochlorothiazide Tablets, 50 mg	Actavis Elizabeth LLC.
ANDA 086710	Aspirin, Butalbital, Caffeine Tablets, 325 mg, 50 mg, and 40 mg.	Do.
ANDA 086813	Prednisone Tablets, 20 mg	Watson Laboratories, Inc.
ANDA 087773	Prednisone Tablets, 10 mg	Do.
ANDA 088348	Hydroxyzine HCl Tablets, 10 mg	Do.
ANDA 088349	Hydroxyzine HCl Tablets, 25 mg	Do.
ANDA 088350	Hydroxyzine HCl Tablets, 50 mg	Do.
ANDA 088497	Methylprednisolone Tablets, 4 mg	Duramed Pharmaceuticals Inc. (an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054.
ANDA 089536	Acetaminophen, Butalbital, and Caffeine Tablets, 325 mg, 50 mg, and 40 mg.	Watson Laboratories, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 30, 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 August 30, 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: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16178 Filed 7–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0519]

Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Health and Human Services (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 ''Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis.'' The purpose of this draft guidance is to help sponsors in the development of anti-rabies virus monoclonal antibody (mAb) cocktails as an alternative to anti-rabies virus immunoglobulin (RIG) as the passive immunization component of post-exposure prophylaxis (PEP) for the prevention of rabies when given immediately after contact with a rabid or possibly rabid animal.

DATES: Submit either electronic or written comments on the draft guidance by September 27, 2021 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–0519 for ''Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis.'' 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. 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: Stephanie Troy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6381, Silver Spring, MD 20993–0002, 240–402–4656.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Rabies: Developing Monoclonal Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis.'' The purpose of this draft guidance is to help sponsors in the development of anti-rabies virus mAb cocktails as an alternative to RIG as the passive immunization component of PEP for the prevention of rabies when given immediately after contact with a rabid or possibly rabid animal. Because of the unique complexities of drug development in this area, extensive discussion with multiple stakeholders has taken place, including a public workshop in 2017 and an advisory committee meeting in 2019. These discussions helped FDA formulate the considerations for rabies mAb cocktail development that are described in this draft guidance.

The draft guidance addresses the following topics:

- Considerations when selecting the mAbs included in the cocktail
- The nonclinical and clinical data needed to support clinical trials of the mAb cocktail in potentially rabies virus-exposed subjects
- The clinical data recommended to support an initial biologics license application submission of the mAb cocktail for a second-line indication in situations where human-derived RIG is not available
- The clinical data recommended to support a first-line indication for the mAb cocktail

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 ''Rabies: Developing Monoclonal

Antibody Cocktails for the Passive Immunization Component of Post-Exposure Prophylaxis.'' 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 collections of information associated with submissions of content and format of labeling for drugs and biologics in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572; the collections of information associated with submissions of investigational new drug applications in 21 CFR part 312 have been approved under OMB control numbers 0910–0014; the collections of information associated with submissions of applications for approval to market a new drug in 21 CFR part 314 have been approved under 0910–0001; the collections of information associated with the reporting and recordkeeping of postmarketing adverse drug experiences have been approved under OMB control numbers 0910–0001, 0910–0230, 0910–0291, and 0910–0645; and the collections of information associated with general licensing provisions for biologics in 21 CFR part 601 have been approved under OMB control number 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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16175 Filed 7–28–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0584]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pilot Survey To Develop Standardized Reporting Forms for Federally Funded Public Health Projects

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 information collection associated with a pilot survey to develop standardized reporting forms for capturing performance data for federally funded public health projects.

DATES: Submit either electronic or written comments on the collection of information by September 27, 2021.

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 27, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 27, 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–2021–N–0584 for ''Pilot Survey to Develop Standardized Reporting Forms for Federally Funded Public Health Projects administered by the Office of Regulatory Affairs (ORA).'' 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