

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Acetaminophen; Benzhydrocodone hydrochloride.
Betamethasone dipropionate; Calcipotriene.
Cefaclor.
Chlorzoxazone (multiple reference listed drugs).
Copper.
Dolutegravir sodium; Rilpivirine hydrochloride.
Doxycycline hyclate.
Encorafenib.
Fluorometholone acetate.
Indocyanine green.
Isoniazid; Pyrazinamide; Rifampin.
Isosorbide dinitrate.
Ketoprofen.
Latanoprost; Netarsudil dimesylate.
Lidocaine.
Lorlatinib.
Lovastatin.
Lutetium dotatate Lu-177.
Medroxyprogesterone acetate.
Meloxicam.
Mifepristone.
Migalastat hydrochloride.
Omadacycline tosylate (multiple reference listed drugs).
Oxymetazoline hydrochloride.
Pimavanserin tartrate.
Sumatriptan succinate.
Tetracaine hydrochloride.
Timolol maleate.

III. Drug Products for Which Revised Draft Product-Specific Guidances are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

Active ingredient(s)
Adapalene (multiple reference listed drugs).
Adapalene; Benzoyl peroxide (multiple reference listed drugs).
Azacitidine.
Baclofen.
Benzoyl peroxide; Clindamycin phosphate (multiple reference listed drugs).
Benzoyl peroxide; Erythromycin (multiple reference listed drugs).
Capsaicin.
Cariprazine hydrochloride.
Clindamycin phosphate (multiple reference listed drugs).
Clindamycin phosphate; Tretinoin.
Clonidine.
Clonidine hydrochloride.
Dapsone (multiple reference listed drugs).
Diclofenac epolamine.
Didanosine.

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS—Continued

Active ingredient(s)
Disopyramide phosphate.
Doxepin hydrochloride.
Estradiol (multiple reference listed drugs).
Estradiol; Levonorgestrel.
Estradiol; Norethindrone acetate.
Ethinyl estradiol; Norelgestromin.
Fentanyl.
Flavoxate hydrochloride.
Granisetron.
Indapamide.
Lidocaine.
Lithium carbonate.
Menthol; Methyl salicylate.
Metformin hydrochloride; Repaglinide.
Methylphenidate.
Mifepristone.
Molindone hydrochloride.
Mycophenolate mofetil.
Nicotine.
Nitrofurantoin, Macrocrystalline.
Nitrofurantoin; Nitrofurantoin, Macrocrystalline.
Nitroglycerin (multiple reference listed drugs).
Oxybutynin (multiple reference listed drugs).
Pimecrolimus.
Prednisolone sodium phosphate.
Rivastigmine.
Roflumilast.
Rotigotine.
Scopolamine.
Selegiline.
Sulfacetamide sodium.
Sulfadiazine.
Tazarotene (multiple reference listed drugs).
Terazosin hydrochloride.
Testosterone.
Tinidazole.
Tipiracil hydrochloride; Trifluridine.
Tretinoin (multiple reference listed drugs).

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to <https://www.regulations.gov> and enter Docket No. FDA-2007-D-0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidances at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: November 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-25326 Filed 11-21-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0736]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the 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 our use of a tracking network to collect and share safety information about animal food from Federal, State, and Territorial Agencies.

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

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 21, 2020. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 21, 2020. 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-2016-N-0736 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet." 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:

Jonnalynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), 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.

Tracking Network for PETNet, LivestockNet, and SampleNet

OMB Control Number 0910-0680—Extension

The Center for Veterinary Medicine and the Partnership for Food Protection developed a web-based tracking network (the tracking network) to allow Federal, State, and Territorial regulatory and public health Agencies to share safety information about animal food. Information is submitted to the tracking network by regulatory and public health Agency employees with membership rights. The efficient exchange of safety information is necessary because it improves early identification and evaluation of a risk associated with an animal food product. We use the information to assist regulatory Agencies to quickly identify and evaluate a risk and take whatever action is necessary to mitigate or eliminate exposure to the risk. Earlier identification and communication with respect to emerging safety information may also mitigate the potential adverse economic impact for the impacted parties associated with such safety issues. The tracking network was developed under the requirements set forth under section 1002(b) of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110-085). Section 1002(b) of the FDAAA required FDA, in relevant part, to establish a pet food early warning alert system.

The tracking network collects: (1) Reports of pet food-related illness and product defects associated with dog food, cat food, and food for other pets, which are submitted via the Pet Event Tracking Network (PETNet); (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses (LivestockNet); and (3) reports about animal food laboratory samples considered adulterated by State or FDA regulators (SampleNet).

PETNet and LivestockNet reports share the following common data elements, the majority of which are drop down menu choices: product details (product name, lot code, product form, and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (*i.e.*, name, telephone number will be captured automatically when

member logs in to the system). For the LivestockNet report, additional data elements specific to livestock animals are captured: Product details (indication of whether the product is a medicated product, product packaging, and intended purpose of the product), class of the animal species affected, and production loss. For PETNet reports, the only additional data field is the animal life stage. The SampleNet reports have the following data elements, many of which are drop down menu choices: Product information (product name, lot code, guarantor information, date and location of sample collection, and product description); laboratory information (sample identification

number, the reason for testing, whether the food was reported to the Reportable Food Registry, who performed the analysis); and results information (analyte, test method, analytical results, whether the results contradict a label claim or guarantee, and whether action was taken as a result of the sample analysis).

Description of Respondents: Voluntary respondents to this collection of information are Federal, State, and Territorial regulatory and public health Agency employees with membership access to the Animal Feed Network.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PETNet	20	5	100	0.25 (15 minutes)	25
LivestockNET	20	5	100	0.25 (15 minutes)	25
SampleNet	20	5	100	0.25 (15 minutes)	25
Total					75

¹ 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: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0197]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Shortages Data Collection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 23, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0491. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Shortages Data Collection System

OMB Control Number 0910-0491—Reinstatement

Under section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act

(FD&C Act) (21 U.S.C. 393(d)(2)), the Commissioner of Food and Drugs is authorized to implement general powers (including conducting research) to carry out effectively the mission of FDA.

After the events of September 11, 2001, and as part of broader counterterrorism and emergency preparedness activities, FDA's Center for Devices and Radiological Health (CDRH) began developing operational plans and interventions that would enable CDRH to anticipate and respond to medical device shortages that might arise in the context of federally declared disasters/emergencies or regulatory actions. In particular, CDRH identified the need to acquire and maintain detailed data on domestic inventory, manufacturing capabilities, distribution plans, and raw material constraints for medical devices that would be in high demand and/or would be vulnerable to shortages in specific disaster/emergency situations or following specific regulatory actions. Such data could support prospective risk assessment, help inform risk mitigation strategies, support real-time decision making by the Department of Health and Human Services during actual emergencies or emergency preparedness exercises, and mitigate or prevent harm to the public health.

The data collection process will consist of an initial telephone call to firms who have been identified as