

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR part; collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Electronic process setup .....	517	1	517	3.08	1,592	\$25,850
806; Submission of corrections and removals .....	1,033	1	1,033	10	10,330	.....
4.102(c)(1)(iii); Submitting correction or removal reports .....	20	1	20	10	200	.....
<b>Total</b> .....	.....	.....	.....	.....	.....	25,850

For respondents who submit corrections and removals using the ESG, the operating and maintenance costs associated with this information collection are approximately \$50 per year to purchase a digital verification

certificate (certificate must be valid for 1 to 3 years). This burden may be reduced if the respondent has already purchased a verification certificate for other electronic submissions to FDA. This burden may also be reduced if

respondents utilize the new PDF template and submit it to the Agency using email, mitigating the need for a digital verification certificate.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1 2</sup>

21 CFR part; collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
806; Records of corrections and removals .....	93	1	93	10 .....	930
4.105(b); recordkeeping by device-led combination products.	279	1	279	0.5 (30 minutes) .....	140
<b>Total</b> .....	.....	.....	.....	.....	1,070

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

<sup>2</sup> Figures have been rounded.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We estimate that 50 percent of submitters will use the ESG to submit the required information. Our estimate of the reporting and recordkeeping burden is based on Agency records and our experience with this program, as well as similar programs that utilize FDA's ESG. For the purposes of estimating the burden, we assume that all respondents who submit corrections and removals using the electronic process will establish a new WebTrader account and purchase a digital verification certificate.

Dated: April 5, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tracking Network for PETNet, LivestockNet, and SampleNet

**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:** Submit written comments (including recommendations) on the collection of information by May 11, 2023.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0680. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASaff@fda.hhs.gov](mailto:PRASaff@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.

#### 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.

In the **Federal Register** of December 22, 2022 (87 FR 78687), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but was not responsive to the information collection topics solicited.

We estimate the burden of this collection of information as follows:

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PETNet .....	5	5	25	0.25 (15 minutes) ...	6.25
LivestockNet .....	5	5	25	0.25 (15 minutes) ...	6.25
SampleNet .....	5	5	25	0.25 (15 minutes) ...	6.25
Total .....	.....	.....	.....	.....	18.75

<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: April 5, 2023.  
**Lauren K. Roth,**  
*Associate Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA–2023–N–1005]**

**Agency Information Collection Activities; Proposed Collection; Comment Request; Focus Groups as Used by the Food and Drug Administration**

**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 generic collection of focus group information as used by FDA for all FDA-regulated products.

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 12, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be