help to provide a reasonable assurance of the safety and effectiveness of devices classified under that regulation. The regulation refers to the document entitled ''Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses,'' which provides recommendations for measures to help provide a reasonable assurance of safety and effectiveness for these reagents. The guidance recommends that sponsors obtain and analyze postmarket data to ensure the continued reliability of their device in detecting the specific novel influenza A virus that it is intended to detect, particularly given the propensity for influenza viruses to mutate and the potential for changes in disease prevalence over time. As updated sequences for novel influenza A viruses become available from the World Health Organization, National Institutes of Health, and other public health entities, sponsors of reagents for detection of specific novel influenza A viruses will collect this information, compare them with the primer/probe sequences in their devices, and incorporate the result of these analyses into their quality management system, as required by 21 CFR 820.100(a)(1). These analyses will be evaluated against the device design validation and risk analysis required by 21 CFR 820.30(g) to determine if any design changes may be necessary.

FDA estimates that one respondent will be affected annually. The respondent will collect this information twice per year; each response is estimated to take 15 hours. This results in a total data collection burden of 30 hours.

The guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

In the **Federal Register** of March 5, 2019 (84 FR 7904), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping regarding reagents for detection of specific novel influenza A viruses	1	2	2	15	30

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

Manufactures are increasingly adopting in silico methods (computational analysis) for the detection of specific novel Influenza A viruses over traditional laboratory techniques. Therefore, few manufactures are using reagents for detection of specific novel influenza A viruses. Based on these industry trends, we estimate a decrease in the number of total annual records and a corresponding decrease of 270 hours in the total burden since our last OMB approval.

Dated: July 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15160 Filed 7–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0297]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prevention of Salmonella Enteritidis in Shell Eggs During Production; Recordkeeping and Registration Provisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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 August 16, 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 0910–0660. 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, *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.

Prevention of *Salmonella Enteritidis* in Shell Eggs During Production—Recordkeeping and Registration Provisions—21 CFR 118.10 and 118.11

OMB Control Number 0910–0660—Extension

Shell eggs contaminated with *Salmonella Enteritidis* (SE) are responsible for more than 140,000 illnesses per year. The Public Health Service Act (PHS Act) (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce such regulations as ''are necessary to prevent the introduction, transmission,

or spread of communicable diseases from foreign countries into the States . . . or from one State . . . into any other State'' (section 361(a) of the PHS Act (42 U.S.C. 264(a))). This authority has been delegated to the Commissioner of Food and Drugs. Under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(a)(4)), a food is adulterated if it is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

Under part 118 (21 CFR part 118), shell egg producers are required to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation. Shell egg producers also are required to maintain records concerning their compliance with part 118 and to register with FDA. As described in more detail with regard to each information collection provision of part 118, each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, must refrigerate, register, and keep certain records. Farms that do not send all of their eggs to treatment are also required to have an SE prevention plan and to test for SE.

Section 118.10 of FDA's regulations (21 CFR 118.10) requires recordkeeping for all measures the farm takes to prevent SE in its flocks. Since many existing farms participate in voluntary egg quality assurance programs, those respondents may not have to collect any additional information. Records are maintained on file at each farm site and examined there periodically by FDA inspectors.

Section 118.10 also requires each farm site with 3,000 or more egg laying hens that sells raw shell eggs to the table egg market, other than directly to the consumer, and does not have all of the shell eggs treated, to design and implement an SE prevention plan.

Section 118.10 requires recordkeeping for each of the provisions included in the plan and for plan review and modifications if corrective actions are taken.

Finally, § 118.11 of FDA's regulations (21 CFR 118.11) requires that each farm covered by 21 CFR 118.1(a) register with FDA using Form FDA 3733. The term ''Form FDA 3733'' refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *https://www.access.fda.gov.* We strongly encourage electronic registration because it is faster and more convenient. The system can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer receives confirmation of electronic registration instantaneously once all the required fields on the registration screen are completed. However, paper registrations will also be accepted. Form FDA 3733 is available for download for registration by mail or CD–ROM.

Recordkeeping and registration are necessary for the success of the SE prevention measures. Written SE prevention plans and records of actions taken due to each provision are essential for farms to implement SE prevention plans effectively. Further, they are essential for us to be able to determine compliance. Information provided under these regulations helps us to notify quickly the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support our enforcement activities.

Description of Respondents: Respondents to this information collection include farm sites with 3,000 or more egg laying hens that sell raw eggs to the table egg market, other than directly to the consumer.

In the **Federal Register** of March 26, 2019 (84 FR 11309), we published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received, however only one was responsive to the four information collection topics solicited. Specifically, the comment suggested that farms could save money by pooling samples while conducting environmental testing, proffering a 2015 research study. The comment continued by suggesting that the testing protocol be adjusted from four 1,000-egg samples to two 1,000 egg samples. We note, however, that testing four 1,000-egg samples over an 8-week period results in approximately a 95 percent probability that a positive egg will be detected from a flock that is producing SE-contaminated eggs with a prevalence of 1 in 1,400, while testing fewer than 4,000 eggs over a period of 8 weeks, as required by 21 CFR 118.7, results in less than a 95 percent probability that a positive egg would be detected from a flock that is producing SE-contaminated eggs at that rate. While we are aware of the referenced research, we decline to relax the current requirements provided for under 21 CFR 118.7 and 118.8 as doing so may reduce certain associated costs that would not provide the same level of protection necessary to ensure the public health. The comment did not suggest a revision to our estimated burden.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Description and 21 CFR section	Number of recordkeepers [2]	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Refrigeration Records, § 118.10(a)(3)(iv)	2,600	52	135,200	0.5 (30 minutes)	67,600
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (positive) [3].	343	52	17,836	0.5 (30 minutes)	8,918
Egg Testing, § 118.10(a)(3)(vii)	331	7	2,317	8.3	19,231
Environmental Testing, § 118.10(a)(3)(v) [3] ..	6,308	23	145,084	0.25 (15 minutes)	36,271
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (negative) [3].	5,965	1	5,965	0.5 (30 minutes)	2,983
Prevention Plan Review and Modifications, § 118.10(a)(4).	331	1	331	10	3,310
Chick and Pullet Procurement Records, § 118.10(a)(2).	4,731	1	4,731	0.5 (30 minutes)	2,366
Rodent and Other Pest Control, § 118.10(a)(3)(ii), and Biosecurity Records, § 118.10(a)(3)(i).	9,462	52	492,024	0.5 (30 minutes)	246,012

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Description and 21 CFR section	Number of recordkeepers [2]	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Prevention Plan Design, § 118.10(a)(1)	350	1	350	20	7,000
Cleaning and Disinfection Records, § 118.10(a)(3)(iii).	331	1	331	0.5 (30 minutes)	166
Total					393,857

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Some records are kept on a by-farm basis and others are kept on a by-house basis.
[3] Calculations include requirements for pullet and layer houses.

We base our estimates for the recordkeeping burden and the reporting burden on our experience with similar recordkeeping activities and the number of registrations and cancellations received in the past 3 years.

The number of recordkeepers estimated in column 2 of table 1 is drawn from estimates of the total number of layer and pullet houses affected by part 118. We assume that those farms that were operating according to recognized industry or State quality assurance plans prior to their compliance date under part 118 were already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore did not experience additional costs to comply with recordkeeping provisions. We found that 59 percent of farms with more than 50,000 layers are members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers are members of quality assurance plans. Thus, we estimate the number of layer farms incurring a new recordkeeping burden because of part 118 to be 2,600, and the number of houses affected to be 4,731.

Prevention plan design (§ 118.10(a)(1)) records are kept on a per farm basis, so we assume that new prevention plan design is only undertaken by new entrants to the industry. Refrigeration records (§ 118.10(a)(3)(iv)) are also kept on a per farm basis so the estimated number of recordkeepers for this provision is 2,600.

Records of chick and pullet procurement (§ 118.10(a)(2)), rodent and other pest control (§ 118.10(a)(3)(ii)), and biosecurity (§ 118.10(a)(3)(i)) are kept on a per house basis, so the estimated number of recordkeepers for these provisions is 4,731.

Records of cleaning and disinfection (§ 118.10(a)(3)(iii)) are also kept on a per house basis, but only need to be kept in the event that a layer house tests environmentally positive for SE. Prevention plan review and modifications (§ 118.10(a)(4)) also need to be performed every time a house tests positive, which we estimate that 7.0 percent test positive. Therefore, the number of recordkeepers for these provisions is calculated to be 331 (4,731 houses × 0.070) annually.

Records of testing, diversion, and treatment (§ 118.10(a)(3)(v) through (viii)) are kept on a per house basis and include records on flocks from pullet houses. We estimate that there are one-third as many pullet houses as there are layer houses. Therefore, the total number of recordkeepers for these provisions is 6,308 (4,731 + (4,731/3)). The number of annual records kept depends on whether houses test positive for SE. Annually, 343 layer and pullet houses ((4,731 layer houses × 0.070) + (4,731/3 pullet houses) × 0.0075)) are expected to test positive and 5,965 are expected to test negative ((4,731 layer houses × 0.930) + (4,731/3 pullet houses) × 0.9925)).

We assume that refrigeration records are kept on a weekly basis on a per farm basis under § 118.10(a)(3)(iv)). We estimate that 2,600 recordkeepers maintain 52 records each for a total of 135,200 records and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for refrigeration records is calculated to be 67,600 hours (135,200 records × 0.5 hour).

We assume that records of testing, diversion, and treatment under § 118.10(a)(3)(v) through (viii) are kept weekly in the event a layer house tests environmentally positive for SE. We estimate that 343 layer and pullet houses test positive and thus 343 recordkeepers maintain 52 records each for a total of 17,836 records and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for testing, diversion, and treatment records in the event of a positive test result is calculated to be 8,918 hours (17,836 records × 0.5 hour).

Given a positive environmental test for SE, we estimate the weighted average number of egg tests per house under § 118.10(a)(3)(vii)) to be 7. We estimate that 331 recordkeepers maintain 7 records each for a total of 2,317 records and that it takes approximately 8.3 hours per recordkeeping. Thus, the total annual burden for egg testing is calculated to be 19,231 hours (2,317 records × 8.3 hours).

We estimate that all 1,577 pullet and 4,731 layer houses not testing prior to their compliance date under part 118 (6,308 recordkeepers) incur the burden of a single environmental test annually under § 118.10(a)(3)(v)). The number of samples taken during the test depends on whether a farm employs the row based method (an average of 12 samples per house) or the random sampling method (32 samples per house). We estimate that roughly 50 percent of the houses affected employ a row based method and 50 percent employ a random sampling method, implying an average of 23 samples per house. The time burden of sampling is estimated on a per swab sample basis. We assume it takes 15 minutes to collect and pack each sample. Thus, the total annual burden for environmental testing is calculated to be 36,271 hours (145,084 records × 0.25 hour).

We estimate that records of testing, diversion, and treatment under § 118.10(a)(3)(v) through (viii) are kept annually in the event a layer house tests environmentally negative for SE. We estimate that 5,965 layer and pullet houses test negative and thus 5,965 recordkeepers maintain 1 record of that testing that takes approximately 0.5 hour per record. Thus, the total annual burden for testing, diversion, and treatment records in the event of a negative test result is calculated to be 2,983 hours (5,965 records × 0.5 hour).

Prevention plan review and modifications under § 118.10(a)(4)) need to be performed every time a house tests positive. We estimate that 331 layer

houses test positive requiring plan review and modifications and that it takes 10 hours to complete this work. Thus, the total annual burden for prevention plan review and modifications in the event of a positive test result is calculated to be 3,310 hours (331 records × 10 hours).

We estimate that chick and pullet procurement records under § 118.10(a)(2) is kept roughly once annually per layer house basis. We estimate that 4,731 layer houses maintain 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for chick and pullet procurement recordkeeping is calculated to be 2,366 hours (4,731 records × 0.5 hour).

We estimate that rodent and other pest control records under § 118.10(a)(3)(ii) and biosecurity records under § 118.10(a)(3)(i) are kept weekly on a per layer house basis. We assume that 4,731 layer houses maintain a weekly record under each provision. Thus, we estimate 9,462 recordkeepers maintain 52 records each for a total of 492,024 records. We estimate a recordkeeping burden of 0.5 hours per record for a total of 246,012 burden hours (492,024 records × 0.5 hour).

New prevention plan design required by § 118.10(a)(1) is only undertaken by new farms and records are kept on a per farm basis. We estimate that there are 350 new farm registrations annually, and we assume that this reflects 350 new farms requiring prevention plan design. This is an increase from our previous estimate based on new registrations received. We estimate that it takes 20 hours to complete this work. Thus, the total annual burden for prevention plan design is calculated to be 7,000 hours (350 records × 20 hours).

Cleaning and disinfection recordkeeping under § 118.10(a)(3)(iii) needs to be performed every time a house tests positive. We estimate that 331 layer houses test positive requiring 1 record each and that it takes approximately 0.5 hour per recordkeeping. Thus, the total annual burden for cleaning and disinfection recordkeeping in the event of a positive test result is calculated to be 166 hours (331 records × 0.5 hour).

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description and 21 CFR section	Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates, § 118.11.	FDA 3733 [2]	350	1	350	2.3	805
Cancellations, § 118.11	FDA 3733	30	1	30	1	30
Total						835

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term "Form FDA 3733" refers to both the paper version of the form and the electronic system known as the Shell Egg Producer Registration Module, which is available at *https://www.access.fda.gov* per § 118.11(b)(1).

This estimate is based on the average number of new shell egg producer registrations and cancellations received in the past 3 years under § 118.11. We estimate that we will receive an average of 350 registrations or updates per year over the next 3 years and that it takes the average farm 2.3 hours to register, taking into account that some respondents completing the registration may not have readily available internet access. Thus, the total annual burden for new shell egg producer registrations or updates is calculated to be 805 hours (350 respondents × 2.3 hours).

We estimate that we will receive 30 cancellations per year over the next 3 years and that cancelling a registration, on average, requires a burden of 1 hour, taking into account that some respondents may not have readily available internet access. Thus, the total annual burden for cancelling shell egg producer registrations is calculated to be 30 hours (30 cancellations × 1 hour).

We have increased our burden estimate for the information collection based on an increase in annual new farm registrations.

Dated: July 10, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15162 Filed 7–16–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Population Affairs; Awards Unsolicited Proposal for the CFDA Number: 93.974

AGENCY: Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Population Affairs (OPA) announces the award of a single-source grant in response to an unsolicited proposal from the University of Northern Colorado, Greely, Colorado. The proposal submitted was not solicited either formally or informally by any federal government official.

FOR FURTHER INFORMATION CONTACT: Diane Foley at *diane.foley@hhs.gov* or by telephone at 240–453–8200.

SUPPLEMENTARY INFORMATION:

Recipient: University of Northern Colorado, Greely, Colorado.

Purpose of the Award: The purpose of this grant is to expand the knowledge base regarding cessation strategies that adolescents and young adults use to maintain their reproductive health. It will provide valuable data on how family planning services can incorporate technology and cessation counseling strategies in primary care medical clinics and other clinic workflows, including Title X clinics.

Amount of Award: $499,385 in Federal Fiscal Year (FFY) 2019 funds and estimated $500,000 in FFY 2020 funds subject to the enactment of appropriations and availability of funds.

Project Period: July 15, 2019–July 14, 2021.

OPA performed an objective review of the unsolicited proposal from the University of Northern Colorado to expand and evaluate the OPTIONS for Integrated Health program. This proposal builds on a previous study, which is the only study in existence that has scientifically demonstrated how the Transtheoretical Model of Health Behavior Change (Prochaska & Velicer) works with sexually active adolescents and young adults. This cutting edge research identified the population of