TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Number of respondents	Numberr of responses per respondent	Total annual responses	Average burden per response	Total hours
3	84	1	84	24	2,016

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

These burden estimates are based on the number of applications FDA received over the past fiscal year.

Dated: January 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01684 Filed 1–27–16; 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; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 information collection provisions of FDA's recordkeeping and registration requirements for shell egg producers.

DATES: Submit either electronic or written comments on the collection of information by March 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2013–N–0297 for Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of *Salmonella* Enteritidis in Shell Eggs During Production—Recordkeeping and Registration Provisions. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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.

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) authorizes the Secretary 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). 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 (the 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 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 requires that each farm covered by § 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 *http://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.

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

Recordkeeping Burden

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	67,600
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (positive) [3]	343	52	17,836	0.5	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	36,271
Testing, Diversion, and Treatment Records, § 118.10(a)(3)(v) through (viii) (negative) [3]	5,965	1	5,965	0.5	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	2,366

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
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	246,012
Prevention Plan Design, § 118.10(a)(1)	300	1	300	20	6,000
Cleaning and Disinfection Records, § 118.10(a)(3)(iii)	331	1	331	0.5	166
Total hours					392,857

[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 are basing 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 are operating according to recognized industry or State quality assurance plans are already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore are not experiencing 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 tests 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 or not houses test positive for SE. Annually, 343 layer and pullet houses ((4,731 layer houses × 0.070) + (4731/3 pullet houses) × 0.0075)) are expected to test positive and 5,965 are expected to test negative ((4,731 layer houses × 0.930) + (4731/3 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 × 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 × 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 × 8.3 hours).

We estimate that all 1,577 pullet and 4,731 layer houses not currently testing (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 employs a row based method and 50 percent employs a random sampling method, implying an average of 23 samples per house. Thus, we estimate that 6,308 recordkeepers take 23 samples each for a total of 145,084 samples. The time burden of sampling is estimated on a per swab sample basis. We estimate that it takes approximately 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 × 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 one 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 × 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 × 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 × 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 × 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 300 new farm registrations annually and we assume that this reflects 300 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 6,000 hours (300 × 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 × 0.5 hour).

Reporting Burden

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description and 21 CFR section	FDA Form number	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Registrations or Updates, § 118.11 ...	Form FDA 3733 [2]	300	1	300	2.3	690
Cancellations, § 118.11	Form FDA 3733 ...	30	1	30	1	30
Total	.....	.....	.....	.....	.....	720

[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 *http://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 300 registrations or updates per year over the next 3 years. Based on the number of cancellations previously received, we estimate that we will receive approximately 30 cancellations per year over the next 3 years.

We estimate 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 690 hours (300 × 2.3 hours).

We estimate cancelling a registration, on average, requires a burden of approximately 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).

Dated: January 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01685 Filed 1–27–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5876–N–02]

Changes in Certain Multifamily Mortgage Insurance Premiums

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: On October 2, 2015, HUD published a notice in the **Federal Register** announcing the mortgage insurance premiums (MIPs) for Federal Housing Administration (FHA) Multifamily, Health Care Facilities, and Hospital mortgage insurance programs that have commitments to be issued or reissued in Fiscal Year (FY) 2016. In the October 2, 2015, notice, HUD stated that the FY 2016 MIPs would be the same as those published for FY 2015. Today's notice announces proposed changes to the FY 2016 MIPs for certain FHA Multifamily Housing Insurance programs for commitments issued or reissued beginning April 1, 2016. MIP rates for mortgage insurance programs under FHA's Office of Healthcare Programs, including health care facilities and hospital insurance programs, will not change. These proposed MIP changes reflect the health of the FHA Multifamily portfolio, an effort to simplify the rate structure, and HUD's commitment to promote its mission initiatives.

DATES: *Comment Due Date:* February 17, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this Notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title and should contain the information specified in the ''Request for Comments'' section. There are two methods for submitting public comments.

1. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451