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Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12824 Filed 5–29–13; 8:45 am]

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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

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 July 1, 2013.

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 Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@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) 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.

On July 9, 2009, FDA published in the **Federal Register** a final rule that established a regulation part 118 (21 CFR part 118) entitled ''Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, Storage, and Transportation'' (74 FR 33030) (the Shell Eggs final rule''). Part 118 requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule 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 § 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.* The Agency strongly encourages electronic registration because it is faster and more convenient. The system the Agency has developed can accept electronic registrations 24 hours a day, 7 days a week. A registering shell egg producer will receive 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 27, 2013 (78 FR 18605), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one letter in response to the notice; however, the letter did not contain comments responsive to the four information collection topics specified in the 60-day notice.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Description and 21 CFR Section	Number of record-keepers [2]	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	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–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–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
Rodent and Other Pest Control, 118.10(a)(3)(ii) and Bio-security Records,118.10(a)(3)(i)	9,462	52	492,024	0.5	246,012
Prevention Plan Design, 118.10(a)(1)	150	1	150	20	3,000
Cleaning and Disinfection Records, 118.10(a)(3)(iii)	331	1	331	0.5	166
Total Hours					389,857

[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.

FDA is retaining most of the estimates published in the Shell Eggs final rule with regard to the estimated number of respondents and the average burden per recordkeeping (74 FR 33030 at 33089 to 33091). FDA bases the remaining recordkeeping burden estimates and the reporting burden estimates on its experience implementing the final rule and the number of registrations and cancellations received in the past 3 years.

The number of recordkeepers estimated in column 2 of Table 1 and all other estimates discussed in this section are drawn from estimates of the total number of layer and pullet houses affected by the Shell Eggs final rule (74 FR 33030 at 33078 to 33080). In the final rule, we assumed that those farms that were operating according to recognized industry or State quality assurance plans were already largely in compliance with the plan design and recordkeeping provisions discussed in this section, and therefore would not experience additional costs to comply with recordkeeping provisions. We found that 59 percent of farms with more than 50,000 layers were members of State or industry quality assurance plans. Fewer than 8 percent of farms with fewer than 50,000 layers were members of quality assurance plans. Thus, we estimated the number of layer farms incurring a new recordkeeping burden because of the Shell Eggs final rule to be 2,600, and the number of houses affected to be 4,731. A detailed breakdown of this estimation is shown in Table 29 of the Shell Eggs final rule (74 FR 33030 at 33078).

Prevention plan design (§ 118.10(a)(1)) records will be kept on a per farm basis but because the Shell Eggs final rule has been fully implemented, FDA assumes that new prevention plan design will only be undertaken by new entrants to the industry. Refrigeration records (§ 118.10(a)(3)(iv)) will also be 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)) will be 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)) will also be kept on a per house basis, but will 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)) will also need to be performed every time a house tests positive. As discussed in Section V.F. of the Shell Eggs final rule (74 FR 33030 at 33078 to 33080), FDA estimated that 7.0 percent will test positive after the provisions of the rule took effect. Therefore, the number of recordkeepers for these provisions is estimated to be 331 (4,731 houses × 0.070) annually.

Records of testing, diversion, and treatment (§ 118.10(a)(3)(v–viii)) will be kept on a per house basis and will include records on flocks from pullet houses. In the Shell Eggs final rule, FDA estimated 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 will be kept on a weekly basis on a per farm basis under § 118.10(a)(3)(iv)). We estimate that 2,600 recordkeepers will maintain 52 records each for a total of 135,200 records and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for refrigeration records is estimated 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–viii)) will be kept weekly in the event a layer house tests environmentally positive for SE. We estimate that 343 layer and pullet houses will test positive and thus 343 recordkeepers will maintain 52 records each for a total of 17,836 records and that it will take 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 estimated 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 will maintain 7 records each for a total of 2,317 records and that it will take approximately 8.3 hours per recordkeeping. Thus, the total annual burden for egg testing is estimated to be 19,231 hours (2,317 × 8.3 hours).

FDA estimates that all 1,577 pullet and 4,731 layer houses not currently testing (6,308 recordkeepers) will 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). For the purposes of this analysis we estimate that roughly 50 percent of the houses affected will employ a row based method and 50 percent will employ a random sampling method, implying an average of 23 samples per house. Thus, we estimate that 6,308 recordkeepers will 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 will take approximately 15 minutes to collect and pack each sample. Thus, the total annual burden for environmental testing is estimated 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–viii)) will be kept annually in the event a layer house tests environmentally negative for SE. We estimate that 5,965 layer and pullet houses will test negative and thus 5,965 recordkeepers will maintain one record of that testing that will take 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 estimated to be 2,983 hours (5,965 × 0.5 hour).

Prevention plan review and modifications under § 118.10(a)(4)) will need to be performed every time a house tests positive. As discussed, we estimate that 331 layer houses will test positive requiring plan review and modifications and that it will take 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 estimated to be 3,310 hours (331 × 10 hours).

We estimate that chick and pullet procurement records under § 118.10(a)(2) will be kept roughly once annually per layer house basis. We estimate that 4,731 layer houses will maintain 1 record each and that it will take approximately 0.5 hour per recordkeeping. Thus, the total annual burden for chick and pullet procurement recordkeeping is estimated 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) will be kept weekly on a per layer house basis. We assume that 4,731 layer houses will maintain a weekly record under each provision. Thus, we estimate 9,462 recordkeepers will 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) will only be undertaken by new farms and records will be kept on a per farm basis. We estimate that there are 150 new farm registrations annually and we assume that this reflects 150 new farms requiring prevention plan design. We estimate that it will take 20 hours to complete this work. Thus, the total annual burden for prevention plan design is estimated to be 3,000 hours (150 × 20 hours).

Cleaning and disinfection recordkeeping under § 118.10(a)(3)(iii) will need to be performed every time a house tests positive. As discussed, we estimate that 331 layer houses will test positive requiring 1 record each and that it will take 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 estimated to be 166 hours (331 × 0.5 hour).

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Description and 21 CFR Section	FDA Form No.	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]	150	1	150	2.3	345
Cancellations, 118.11	Form FDA 3733	15	1	15	1	15
Total	.....	.....	.....	.....	.....	360

[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 FDA's experience implementing the Shell Eggs final rule and the average number of new Shell Egg Producer registrations and cancellations received in the past 3 years under § 118.11. Based on FDA experience with implementing the registration provisions of the Shell Eggs final rule, which had staggered compliance dates and gave producers with fewer than 50,000 but at least 3,000 laying hens until July 9, 2012, to register (74 FR 33030 at 33034), FDA expects that it will receive fewer registrations or updates each year over the next 3 years,

reflecting compliance with the final rule's registration deadlines. FDA estimates that it will receive 200 registrations or updates in 2013, 150 registrations or updates in 2014 and 100 registrations or updates in 2015, for an average of 150 registrations or updates per year over the next 3 years. FDA received 12 cancellations in 2011 and 19 cancellations in 2012. Based on this experience, FDA estimates that it will receive approximately 15 cancellations per year over the next 3 years.

FDA estimated in the Shell Eggs final rule that listing the information required by the final rule and presenting it in a format that will meet the Agency's registration regulations will require a burden of approximately 2.3 hours per average registration. As detailed in section V.F. of the final rule (see 74 FR 33030 at 33080), FDA estimates that it will take 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 estimated to be 345 hours (150 × 2.3 hours).

FDA estimates cancelling a registration will, on average, require 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 estimated to be 15 hours (15 cancellations × 1 hour).

Dated: May 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–12790 Filed 5–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 22, 2013, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm*; under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On July 22, 2013, the committee will discuss the Assessment of SpondyloArthritis international Society classification criteria for axial spondyloarthritis and the implications of using these criteria for drug approval.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 8, 2013. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 27, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 28, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 24, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–12839 Filed 5–29–13; 8:45 am]

BILLING CODE 4160–01–P