6. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Annual Report of Physician-Owned Hospital Ownership and/or Investment Interest; *Use:* Section 6001 of the Affordable Care Act (ACA) requires Medicare hospitals to report whether they have any physician owners including immediately family members of the physician.

Currently the CMS 855A captures basic ownership/managerial information on providers. The CMS 855A was revised in July 2011 and a specific attachment designed to capture physician-owned hospital ownership and investment interest data was added to the form. The attachment is being removed from the CMS 855A application because the annual reporting requirement for physician-owned hospitals is not required for Medicare enrollment processing. This physician-owned hospital data collection is mandated to be reported on an annual basis. Additionally, the ACA prohibits the expansion of current physician-owned hospitals and banned the establishment of new ones making the CMS 855A the improper method to collect this required annual report.

CMS is requesting the physician-owned hospital ownership information, investment information or both, previously collected in Attachment 1 of the CMS 855A enrollment application to become a stand-alone form with a unique OMB number for the following reasons:

- The physician-owned data collection has a small targeted audience of approximately 140 physician-owned hospitals nationwide.
- The physician-owned data collection is required annually, as noted above.
- The data required under section 6001 is more specific than the data currently collected on the CMS–855A provider enrollment application.
- The data is not required for Medicare provider enrollment purposes.

Form Number: CMS–855 (POH)(OCN: 0938-New); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 140; *Total Annual Responses:* 140; *Total Annual Hours:* 140. (For policy questions regarding this collection contact Kim McPhillips at 410–786–5374. For all other issues call 410–786–1326.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Hospital and Health Care Complexes and Supporting Regulations in 42 CFR 413.20 and 413.24; *Use:* Medicare Part A institutional providers must provide adequate cost data to receive Medicare reimbursement (42 CFR 413.24(a)). Providers must submit the cost data to their Medicare Fiscal Intermediary (FI)/Medicare Administrative Contractor (MAC) through the Medicare cost report (MCR). We are submitting a revision of the Hospital and Hospital Health Care Complex Cost Report, Form CMS–2552–10. Form CMS 2552–10 is used by hospitals participating in the Medicare program to report the health care costs to determine the amount of reimbursable costs for services rendered to Medicare beneficiaries. The revisions were caused by legislative requirements in the Patient Protection and Affordable Care Act of 2010 and the Temporary Payroll Tax Cut Continuation Act of 2011. *Form Number:* CMS–2552–10 (OCN: 0938–0050); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 6,171; *Total Annual Responses:* 6,171; *Total Annual Hours:* 4,153,083. (For policy questions regarding this collection contact Nadia Massuda at 410–786–5834. For all other issues call 410–786–1326.)

8. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection. *Title of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments. *Use:* CMS will use the data to make risk adjusted payment under Parts C. MA and MA–PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS–HCC and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS–10062 (OMB 0938–0838). *Frequency:* Quarterly. *Affected Public:* Private Sector (business or other for-profit and not-for-profit institutions). *Number of Respondents:* 766. *Total Annual Responses:* 830,000. *Total Annual Hours:* 40,650. (For policy questions regarding this collection contact Michael Massimini at 410–786–1566. For all other issues call 410–786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by July 9, 2013:

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 6, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2013–11035 Filed 5–9–13; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1181]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medicated Feed Mill License Application; Extension

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 June 10, 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 0910–0337. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@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.

Medicated Feed Mill Licensing Application—21 CFR Part 515 (OMB Control Number 0910–0337)—Extension

The Animal Drug Availability Act (ADAA) of October 9, 1996, amended section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b) to replace the system for the approval of specific medicated feed with a general licensing system for feed mills. Before passage of the ADAA, medicated feed manufacturers were required to obtain approval of Medicated Feed Applications (MFAs) in order to manufacture certain types of medicated feeds. An individual approved MFA was required for each and every applicable medicated feed. The ADAA streamlined the paperwork process for gaining approval to manufacture medicated feeds by replacing the MFA system with a facility license for each medicated feed manufacturing facility. Implementing regulations are at 21 CFR part 515.

In the **Federal Register** of December 21, 2012 (77 FR 75635), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received; however, it was unrelated to the information collection.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section and activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medicated Feed Mill License Application Using Form FDA 3448 (515.10(b)).	20	1	20	0.25 (15 minutes)	5
Supplemental Feed Mill License Application Using Form FDA 3448 (515.11(b)).	40	1	40	0.25 (15 minutes)	10
Voluntary Revocation of Medicated Feed Mill License (515.23).	40	1	40	0.25 (15 minutes)	10
Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)).	1	1	1	4	4
Total					29

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	No. of recordkeepers	No. of responses per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Maintenance of Records for Approved Labeling for Each ''Type B'' and ''Type C'' Labeling (510.305).	950	1	950	0.03 (2 minutes)	28.5

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

Estimated annual reporting burden on industry is 29 hours as shown in table 1. Industry estimates it takes about 15 minutes (0.25) to submit the application. We estimate 100 original and supplemental applications, and voluntary revocations for a total of 25 hours (100 submissions x 0.25 (15 minutes)). An additional 4 hours is added for the rare notice of opportunity for a hearing to not approve or revoke an application. Finally, we estimate 28.5 hours for maintaining and retrieving labels as required by 21 CFR 510.305. We estimated 2 minutes (0.03 hour) for each of approximately 950 licensees. Total burden for reporting and recordkeeping would be 57.5 hours.

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11126 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0145]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *ila.mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 5, 2012, the Agency submitted a proposed collection of information entitled ''Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0726. The approval expires on December 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11128 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On February 11, 2013, the Agency submitted a proposed collection of information entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0582. The approval expires on April 30, 2016. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: May 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–11125 Filed 5–9–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0523]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 contained in the requirements for reporting information about authorized generic drugs in an annual report.

DATES: Submit either electronic or written comments on the collection of information by *July 9, 2013.*

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–