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–

400B, Rockville, MD 20857, 301–796–7726, *Ila.mizrachi@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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites 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.

**Applications for Food and Drug Administration Approval To Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs—(OMB Control Number 0910–0646)—Extension**

In the **Federal Register** of July 28, 2009 (74 FR 37163), FDA published a final rule that required, under § 314.81(b)(2)(ii)(*b*) (21 CFR 314.81(b)(2)(ii)(*b*)), the holder of a new drug application (NDA) to notify the Agency if an authorized generic drug is marketed by clearly including this information in annual reports in an easily accessible place and by sending a copy of the relevant portion of the annual reports to a central contact point. We took this action as part of our implementation of the Food and Drug Administration Amendments Act (Public Law 110–85), which requires that FDA publish a list of all authorized generic drugs included in an annual report after January 1, 1999, and that the Agency update the list quarterly. We initially published this list on June 27, 2008, on the Internet and notified relevant Federal Agencies that the list was published, and we will continue to update it.

Based on the number of annual reports the Agency currently receives under § 314.81(b)(2) containing authorized generic drug information, we estimate that we will receive approximately 500 annual reports containing the required information on authorized generic drugs. Based on the number of sponsors that currently submit these annual reports, we estimate that approximately 70 sponsors will submit these 500 annual reports. We estimate that each sponsor will need approximately 30 minutes to include the required information on authorized generic drugs in each annual report.

We also estimate that we will receive authorized generic drug information on first marketed generics in approximately 20 annual reports from approximately 20 sponsors, and that each sponsor will need approximately 1 hour to include the required information in each annual report.

We also estimate that we will receive a copy of that portion of each annual report containing the authorized generic drug information for approximately 500 annual reports from approximately 70 sponsors, and that each sponsor will need approximately 3 minutes to submit a copy of that portion of each annual report containing the authorized generic drug information.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR 314.81(b)(2)(ii)(*b*) | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Submission of authorized generic drug information in each annual report. | 70 | 7 | 490 | 0.5 (30 minutes) | 245 |
| Submission of authorized generic drug information on first marketed generics in an annual report. | 20 | 1 | 20 | 1 | 20 |
| Submission of a copy of that portion of each annual report containing authorized generic drug information. | 70 | 7 | 490 | 0.05 (3 minutes) | 25 |
| Total | | | | | 290 |

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

Dated: May 6, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–11127 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–0001]**

### Anesthetic and Analgesic Drug Products 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:* Anesthetic and Analgesic Drug Products Advisory Committee.

*General Function of the Committee:* To provide advice and