entitlement to Part A and Supplementary Medical Insurance (Part B). *Form Number:* CMS–18F5 (OMB#: 0938–0251); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 50,000; Total *Annual Responses:* 50,000; *Total Annual Hours:* 12,495. (For policy questions regarding this collection contact Naomi Rappaport at 410–786–2175. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendment (CLIA) of 1988 and Supporting Regulations in 42 CFR 493.1–.2001; *Use:* The information collection requirements in 42 CFR part 493 outline the requirements necessary to determine an entity's compliance with CLIA. CLIA requires laboratories that perform testing on human beings to meet performance requirements (quality standards) in order to be certified by the Department of Health and Human Services (DHHS). DHHS conducts inspections to determine a laboratory's compliance with CLIA requirements. CLIA implements the certificate, laboratory standards and inspection requirements; *Form Number:* CMS–R–26 (OMB#: 0938–0612); *Frequency:* Occasionally; *Affected Public:* Federal Government; State, Local, or Tribal Governments; Private Sector: Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 168,688; *Total Annual Responses:* 756,240; *Total Annual Hours:* 11,363,280. (For policy questions regarding this collection contact Raelene Perfetto at 410–786–6876. 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 E-mail 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.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *January 18, 2011.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–6974. E-mail: *OIRA_submission@omb.eop.gov.*

Dated: December 10, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–31599 Filed 12–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–102 and CMS–105, CMS–10241, CMS–10261, CMS–10185, and CMS–10340]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments of 1988 (CLIA) Budget Workload Reports and Supporting Regulations in 42 CFR 493.1-.2001; *Use:* The collected information will be used by CMS to determine the amount of Federal reimbursement for surveys conducted. Use of the information includes program evaluation, audit, budget formulation and budget approval. Form CMS–102 is a multi-purpose form designed to capture and record all budget and expenditure data. Form CMS–105 captures the annual projected CLIA workload that the State survey agency will accomplish. It is also used by the CMS regional office to approve the annual projected CLIA workload. The information is required as part of the section 1864 agreement with the State; *Form Numbers:* CMS–102 and CMS–105 (OMB#: 0938–0599); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 4,500. (For policy questions regarding this collection contact Carla Ausby at 410–786–2153. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Annual State Report and Annual State Performance Rankings; *Use:* Section 6001(f) of the Deficit Reduction Act (DRA) requires CMS to contract with a vendor to conduct a monthly national survey of retail prescription drug prices and to report the prices to the States. These national average prices may be used as a benchmark by the States for the management of their prescription drug programs. The DRA also requires that the States submit pricing information for the 50 most widely prescribed drugs so that the States' prices can be compared to the national average prices obtained from the survey. The States pricing information will be compared and the States will be ranked. The Act also requires that States report their drug utilization rates for noninnovator multiple source (generic) drugs, their payment rates under their State plan, and their dispensing fees. The template has been developed to facilitate data collection; *Form Number:* CMS–10241 (OMB#: 0938–1041); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 765. (For policy questions regarding this collection contact Joseph Fine at 410–786–2128. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Part C Medicare Advantage (MA) Reporting Requirements and Supporting Regulations; *Use:* CMS has authority to establish reporting requirements for Medicare Advantage Organizations (MAO's) as described in 42 CFR § 422.516 (a). Each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the cost of its operations, patterns of service utilization, availability, accessibility,

and acceptability of its services, developments in the health status of its enrollees, and other matters that CMS may require. Data collected via Medicare Part C Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the benefits provided by MA plans to enrollees. *Form Number:* CMS–10261 (OMB# 0938–1054); *Frequency:* Yearly, Quarterly; Affected *Public:* Business or other for-profits; *Number of Respondents:* 588; *Total Annual Responses:* 1158; *Total Annual Hours:* 245,528. (For policy questions regarding this collection contact Terry Leid at 410–786–8973. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements and Supporting Regulations; *Use:* 42 CFR part 423, § 423.514, requires each Part D Sponsor to have an effective procedure to provide statistics indicating: the cost of its operations, the patterns of utilization of its services, the availability, accessibility, and acceptability of its services, information demonstrating it has a fiscally sound operation and other matters as required by CMS. In addition, subsection 423.505 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit Group. *Form Number:* CMS–10185 (OMB#: 0938–0992); *Frequency:* Yearly, Quarterly, Semi-Annually; *Affected Public:* Private sector, business or other for-profit; *Number of Respondents:* 2993; Total *Annual Responses:* 48,490; *Total Annual Hours:* 128,754. (For policy questions regarding this collection contact LaToyia Grant at 410–786–5434. For all other issues call 410–786–1326.)

5. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Collection of Encounter Data from Medicare Advantage Organizations; *Use:* The Centers for Medicare and Medicaid Services (CMS) intends to collect encounter data, or data on each item or service delivered to an enrollee, from Medicare Advantage Organizations. Medicare Advantage organizations will obtain this data from providers. CMS would collect the data electronically from Medicare Advantage Organizations via the Health Insurance Portability and Accountability Act (HIPAA) compliant standard Health Care Claims transactions for professional data and institutional data. The information is used to submit health care claims or equivalent health encounter information, carry out health plan enrollments and disenrollments, determine health plan eligibility, send and receive health care payment and remittance advices, transmit health plan premium payments, determine health care claim status, provide referral certifications and authorizations, and coordinate the benefits for individuals who have more than one health plan. *Form Number:* CMS–10340 (OMB#: 0938–New); *Frequency:* Weekly; *Affected Public:* Private sector; businesses or other for-profits; *Number of Respondents:* 678; Total *Annual Responses:* 384,041,063; *Total Annual Hours:* 768. (For policy questions regarding this collection contact Sean Creighton at 410–786–9302 or Deondra Moseley at 410–786–4577. 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 at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or E-mail 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 *February 15, 2011:*

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: December 10, 2010.

Martique Jones,

Director, Regulations Development Division-B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010–31541 Filed 12–16–10; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0627]

Agency Information Collection Activities; Proposed Collection; Comment Request; Application for Food and Drug Administration Approval to Market a New Drug

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 requirements governing applications for FDA approval to market a new drug.

DATES: Submit either electronic or written comments on the collection of information by February 15, 2011.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal