

continue its use of the BPT for the collection of information for CY2014 through CY2016. *Form Number:* CMS–10142 (OCN: 0938–0944); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 555; *Total Annual Responses:* 4,995; *Total Annual Hours:* 149,850. (For policy questions regarding this collection contact Diane Spitalnic at 410–786–5745. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Plan Benefit Package (PBP) and Formulary Submission for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization.

After receiving OMB clearance in spring 2000, CMS implemented the PBP as part of the Contract Year (CY) 2001 Adjusted Community Rate Proposal (ACRP) process. In addition, information collected via the PBP and formulary has been used to support the marketing material review process, the National Medicare Education Program, and other program oversight and development activities. For instance, the PBP software automatically generates the standardized sentences for the Summary of Benefits (SB) by using the plan benefit package data entered into the PBP software by the organization's user. These standardized sentences are used by the MA organizations in their SB marketing materials and by CMS to generate plan benefits data for display in the *Medicare & You* handbook and on the [www.medicare.gov](http://www.medicare.gov) Web site.

CMS is requesting to continue its use of the PBP software and formulary submission for the collection of benefits

and related information for CY 2014 through CY 2016. CMS estimates that 578 MA organizations and 63 PDP organizations will be required to submit the plan benefit package information in CY 2014. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. *Form Number:* CMS–R–262 (OCN: 0938–0763); *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 641; *Total Annual Responses:* 6,169; *Total Annual Hours:* 56,708. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209. 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.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>, or Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 February 19, 2013. OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* (202) 395–6974, *Email:* [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov).

Dated: January 11, 2013.

**Martique Jones,**

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

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

[Document Identifier: CMS–10437]

#### **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:* New collection; *Title of Information Collection:* Generic Social Marketing & Consumer Testing Research; *Use:* The purpose of this submission is to request an Information Collection Request (ICR) generic clearance for a program of consumer research aimed at a broad audience of those affected by CMS programs including Medicare, Medicaid, Children's Health Insurance Program (CHIP), and health insurance exchanges. This program extends strategic efforts to reach and tailor communications to beneficiaries, caregivers, providers, stakeholders, and any other audiences that would support the Agency in improving the functioning of the health care system, improve patient care and outcomes, and reduce costs without sacrificing quality of care. With the clearance, CMS will create a fast track, streamlined, proactive process for collection of data and utilizing the feedback on service delivery for continuous improvement of communication activities aimed at diverse CMS audiences.

The generic clearance will allow rapid response to inform CMS initiatives using a mixture of qualitative and quantitative consumer research strategies (including formative research studies and methodological tests) to improve communication with key CMS audiences. As new information resources and persuasive technologies are developed, they can be tested and evaluated for beneficiary response to the materials and delivery channels. Results will inform communication development and information architecture as well as allow for continuous quality improvement. The overall goal is to maximize the extent to which consumers have access to useful sources of CMS program information in

a form that can help them make the most of their benefits and options

The activities under this clearance involve social marketing and consumer research using samples of self-selected customers, as well as convenience samples, and quota samples, with respondents selected either to cover a broad range of customers or to include specific characteristics related to certain products or services. All collection of information under this clearance will utilize a subset of items drawn from a core collection of customizable items referred to as the Social Marketing and Consumer Testing Item Bank. This item bank is designed to establish a set of pre-approved generic question that can be drawn upon to allow for the rapid turn-around consumer testing required for CMS to communicate more effectively with its audiences. The questions in the item bank are divided into two major categories. One set focuses on characteristics of individuals and is intended primarily for participant screening and for use in structured quantitative on-line or telephone surveys. The other set is less structured and is designed for use in qualitative one-on-one and small group discussions or collecting information related to subjective impressions of test materials. A Study Initiation Request Form detailing each specific study (description, methodology, estimated burden) conducted under this clearance will be submitted before any testing is initiated. Results will be compiled and disseminated so that future communication can be informed by the testing results. We will use the findings to create the greatest possible public benefit. *Form Number:* CMS-10437 (OCN: 0938-New); *Frequency:* Yearly; *Affected Public:* Individuals. *Number of Respondents:* 41,592. *Number of Responses:* 28,800. *Total Annual Hours:* 21,488. (For policy questions regarding this collection contact Chris Koepke at 410-786-5877. 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](mailto: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 March 18, 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: January 11, 2013.

**Martique Jones,**

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0007]

#### Generic Drug User Fee—Active Pharmaceutical Ingredient and Finished Dosage Form Facility Fee Rates for Fiscal Year 2013

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rate for the generic drug active pharmaceutical ingredient (API) and finished dosage form (FDF) facilities user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), enacted the Food and Drug Administration Safety and Innovation Act, as further amended by the FDA User Fee Corrections Act of 2012, authorizes FDA to assess and collect user fees for certain applications and supplements associated with human generic drug products, on applications in the backlog as of October 1, 2012, on finished dosage form (FDF) and active pharmaceutical ingredient (API) facilities, and on Type II API drug master files (DMF) to be made available for reference. GDUFA directs FDA to establish each year the generic drug user fee rates for the upcoming year. In the first year of GDUFA (FY 2013), some rates will be published in separate

**Federal Register** notices because of the timing specified in the statute. Each year thereafter the GDUFA fee rates will be published 60 days before the start of the fiscal year. This document establishes the FY 2013 rate for API and FDF facility fees. These fees are due on March 4, 2013.

#### FOR FURTHER INFORMATION CONTACT:

David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., PI50, Rm. 210J, Rockville, MD 20850, 301-796-7103.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Sections 744A and 744B of the FD&C Act, as added by GDUFA (21 U.S.C. 379j-41 and 379j-42), establish user fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012; (2) certain types of applications and supplements associated with human generic drug products; (3) certain facilities where human generic drug APIs and FDFs are produced; and (4) certain Type II API DMFs associated with human generic drug products. This notice focuses on the API and FDF facility fees.

##### II. Fee Revenue Amount for FY 2013

The total fee revenue amount for FY 2013 is \$299,000,000, as set in the statute. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fees. GDUFA states that the backlog fee will make up \$50,000,000 of the total revenue collected for FY 2013. Therefore, the rest of the fees will make up a percentage of the remaining \$249,000,000 of the total fee revenue. For more information about GDUFA, please refer to the FDA Web site (<http://www.fda.gov/gdufa>). The API and FDF facility fee calculations for FY 2013 are described in this document.

##### III. Foreign Differential

Under GDUFA, the fee for a facility located outside the United States and its territories and possessions shall be not less than \$15,000 and not more than \$30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions. For FY 2013 FDA has determined that the differential for foreign facilities will be \$15,000. The differential may be adjusted in future years.