the address below, no later than 5 p.m. on *January 14, 2009.*

OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Date: *December 5, 2008.*

Michelle Shortt,

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

[FR Doc. E8–29542 Filed 12–12–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10110, CMS–R–250 and CMS–668B]

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:* Revision of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of the Social Security Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted to CMS. CMS will utilize the ASP data to determine the Medicare Part B drug payment amounts. *Form Number:* CMS–10110 (OMB# 0938–0921); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 28,800.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* MPAF Data and Supporting Regulations in 42 CFR 413.337, 413.343, 424.32 and 483.20; *Use:* Resident assessment information that Skilled Nursing Facilities (SNFs) are required to submit is described under section 42 CFR 413.343 and 483.20. The manner necessary to administer the payment rate methodology is described under section 42 CFR 413.337. An assessment form comprised of a subset of resident assessment information has been developed for use by SNFs to satisfy Medicare payment requirements, in lieu of a full Minimum Data Set. The associated burden is the time the SNF staff is required to complete the Medicare PPS Assessment Form (MPAF), SNF staff time to encode, and SNF staff time spent in transmitting the data. *Form Number:* CMS–R–250 (OMB# 0938–0739); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local, or Tribal Governments, and Federal Governments; *Number of Respondents:* 15,039; *Total Annual Responses:* 3,834,945; *Total Annual Hours:* 2,704,764.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777; *Use:* This form is used by the State agency to determine a laboratory's compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This information is needed for a laboratory's CLIA certification and recertification. *Form Number:* CMS–668B (OMB# 0938–0653); *Frequency:* Biennially; *Affected Public:* Business or other for-profits and Not-for-profit institutions. State, Local, or Tribal Government, Federal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 2,625.

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 13, 2009:*

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 5, 2008.

Michelle Shortt,

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

[FR Doc. E8–29543 Filed 12–12–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0602]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

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 and to allow 60 days for

public comment in response to the notice. This notice solicits comments on a study of the impact of the presence of coupons offering price incentives or rebates on consumers' perceptions of product risks and benefits in direct-to-consumer (DTC) print ads.[1] Notice of proposed information collection for this project was previously published on February 6, 2006 (71 FR 6077) and withdrawn. This revised notice replaces the previous notice.

DATES: Submit written or electronic comments on the collection of information by February 13, 2009.

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 (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3792.

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 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.

Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

FDA recognizes that the manufacturers, packers, and distributors (sponsors) of prescription human and animal drugs, including biological products for humans, have a First Amendment right to engage in the truthful and non-misleading advertising of their products. An advertisement is misleading, however, if it fails to disclose certain information about the advertised product's uses and risks. Thus, for prescription drugs and biologics, the act requires advertisements to contain ''information in brief summary relating to side effects, contraindications, and effectiveness'' (21 U.S.C. 352(n)). FDA is responsible for enforcing the act and implementing regulations.

FDA regulations require that prescription drug advertisements that make claims about a product must also include risk information in a ''balanced'' manner (21 CFR 202.1(e)(5)(ii)), both in terms of the content and presentation of the information. Advertisements that draw attention to the name of the product but do not make representations about the product's indication(s) or dosage recommendations are called reminder advertisements. As a general matter, reminder ads may mention the proprietary and established name of the product and (optionally) contain information about the product's ingredients, dosage form, quantity, price, and manufacturer (21 CFR 202.1(e)(2)(i)). Other written, printed, or graphic information is not prohibited in reminder ads as long as that information does not make a representation or suggestion relating to the product beyond those permitted.

Reminder ads allow sponsors to distribute price sheets, pens, notepads and other minor giveaways featuring the name of the drug product to physicians and other healthcare professionals without requiring a full disclosure of the product's risks. As DTC promotion has increased, sponsors have chosen to create reminder ads for consumers.

On November 1 and 2, 2005, the agency held a part 15 public hearing (70 FR 54054, September 13, 2005) on the topic of direct-to-consumer advertising of prescription drugs and restricted medical devices. During the hearing, the agency received several comments in connection with the potential impact of coupons and other price incentives on consumer perceptions of DTC-advertised products. Sponsors may use ads as a vehicle to offer price incentives to consumers (e.g., ''free trial,'' ''buy six get one free''). Coupon promotions are widely used in many product categories and have been the topic of many academic studies. Certain types of coupons, most notably those that appear in the body of an advertisement itself (i.e., are embedded in the advertisement), can positively affect perceptions of the brand.[2]

People tend to rate owned objects more favorably than those they do not own, even when those objects have been assigned to them at random.[3] This has been termed the ''mere ownership'' or ''mere possession'' effect. An interesting extension of this effect is provided in research by Sen and Johnson[4] which has shown that consumers rate a product more favorably when they are simply given a gift certificate or a coupon for that product or service. Other research has examined the effect of warranties. People who viewed an ad with a high warranty perceived the product as being less risky compared to people who saw an ad with a medium or low warranty.[5]

Based on this body of consumer research, the inclusion of a coupon or other price incentive in the body of a DTC ad may affect consumers' perceptions of the risks and benefits of

[1] While the Federal Food, Drug, and Cosmetic Act (the act) provides FDA with authority to regulate prescription drug advertisements that are false or misleading, the act does not provide FDA with the authority to regulate the pricing of prescription drugs. Thus, FDA is merely interested in studying the impact, if any, of the presence of coupons in DTC advertisements on consumers' perceptions of product risks and benefits, and recognizes that it does not actually regulate the dollar or other incentive amount of coupons, price incentives, or rebate offers with respect to how they affect the price of prescription drugs or biological products.

[2] LeClerc, France and John D.C. Little, ''Can Advertising Copy Make FSI Coupons More Effective?'' *Journal of Marketing Research*, 34(4), 473-484, 1997.

[3] Beggan, James K., ''On the Social Nature of Nonsocial Perception: The Mere Ownership Effect,'' *Journal of Personality and Social Psychology*, 62(2), 229-237, 1992.

[4] Sen, Sankar and Eric J. Johnson, ''Mere-Possession Effects Without Possession in Consumer Choice,'' *Journal of Consumer Research*, 24 (June), 105-117, 1997.

[5] Shimp, Terrence A. and William O. Bearden, ''Warranty and Other Extrinsic Cue Effects on Consumers' Risk Perceptions,'' *Journal of Consumer Research*, 9 (June), 38-47, 1982.

the prescription drug. For instance, consumers may assign more weight to benefit claims in cases where a coupon or other price incentive is embedded in the advertisement. For ''simple'' consumer products, coupons and free trial offers may enable the customer to test new products while minimizing their financial risk of testing the product. For products that consumers can readily test and ones where performance can be adequately verified (termed ''search'' goods by economists), coupons and free trial offers provide both the consumer and manufacturer an efficient mechanism for matching consumers and products. For more complex products such as prescription drugs where supervision of a physician is required to evaluate both appropriateness and performance, coupons and free trial offers may send different signals.

The proposed exploratory study will examine what impact, if any, the presence of coupons in DTC advertisements may have on consumers' perceptions of product risks and benefits and the overall impression of the product in DTC full-product and reminder advertisements.[6]

Design Overview

This study will employ a between-subjects crossed factorial design and will focus on consumer print advertising. Fifteen print advertisements will be created using three levels of ad type and five levels of promotional offer. Thus, the factors will be ad type (DTC print reminder; DTC print full product; over-the-counter (OTC) print full product) and offer type (free trial offer; buy one, get one free; money off prescription/purchase cost; money back guarantee; no promotion). Product name and indication will be constant across conditions. Side effect and risk information will be constant across full product DTC ad conditions. Participants will be asked to read a single print advertisement for a new drug. After reading the advertisement, they will be asked questions about their evaluation of the information presented in the advertisement.

Factors

1. Participants: Consumers will be screened and recruited by the contractor to be currently diagnosed with insomnia or at risk of developing insomnia. Participants will be randomly assigned to experimental cells. Each condition will be balanced with respect to gender.

Because this is the first investigation of this issue with DTC ads, we chose to limit our investigation to one disease condition. We chose to accept this decrease in generality to maximize our ability to detect a subtle difference between promotion types. Participants will be screened to represent a range of education levels (some college or less vs. completed college or more). Because the task presumes basic reading abilities, all participants will have English as their primary language and, as appropriate, be required to have reading glasses when participating in the study.

2. Type of Ad: The following three types of ads will be tested: (1) A full-product ad for a prescription drug, (2) a reminder ad for a prescription drug, and (3) an ad for an OTC drug. An ad for an OTC drug, which typically includes benefit but not risk information, is included to see if prior research findings in the area of consumer package goods can be replicated.

3. Type of Promotion: The following five types of promotions will be tested: (1) Free trial offer; (2) buy one, get one free; (3) money-off prescription/purchase cost; (4) money back guarantee; and (5) a no promotion condition. With the exception of buy one, get one free, these are promotional variations that have been used in drug advertising. We ask for comment on other promotional types that could be tested.

Procedure

Participants will be shown one ad, for example, a reminder ad for a prescription drug with a free-trial offer coupon embedded. Then the participant will be asked to answer questions examining a number of important perceptions about the product, including perceived riskiness of the drug, likelihood of benefits, and behavioral intent (talking to doctor, product purchase). Finally, demographic and health care utilization information will be collected.

Interviews are expected to last approximately 15 minutes. A total of 1,350 participants will be involved. This will be a one-time (rather than annual) collection of information.

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

FDA estimates that 2,025 individuals will need to be screened to obtain a respondent sample of 1,350. The screener is expected to take 30 seconds, for a total screener burden of 17 hours. The 1,350 respondents will then be asked to respond to a series of questions about the advertisement. We estimate the response burden for the survey to be 15 minutes, for a burden of 337.5 hours. The estimated total burden for this data collection effort is 354.5 hours.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
2,025 (screener)	1	2,025	.008	17
1,350 (questionnaire)	1	1,350	.25	337.5
Total		3,375		354.5

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

[6] As noted previously in this document, FDA does not have the authority to regulate prescription drug pricing and we will not be examining prescription drug prices.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29517 Filed 12–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

The Health Resources and Services Administration (HRSA) is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

Pursuant to section 100.2 of the VICP's implementing regulation (42 CFR Part 100), the Secretary announces that the revised average cost of a health insurance policy under the VICP is $382.30 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the United States Court of Federal Claims. Such notice was delivered to the Court on November 12, 2008.

Dated: December 8, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–29627 Filed 12–12–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: February 10, 2009.

Open: 8 a.m. to 12 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, C-Wing, Room 10, Bethesda, MD 20892.

Contact Person: Stephen C. Mockrin, PhD., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892, (301) 435–0260, *mockrins@nhlbi.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/index.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 8, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–29537 Filed 12–12–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: January 9, 2009.

Time: 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate the scientific and technical merit of applications seeking to use the resources and facilities of the CIDR.

Place: Embassy Suites Hotel, 4300 Military Road, NW., Chevy Chase, MD 20015.

Contact Person: Camilla E. Day, PhD., Scientific Review Officer, CIDR National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892 301–402–8837, *camilla.day@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 5, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–29428 Filed 12–12–08; 8:45 am]

BILLING CODE 4140–01–M