subcommittee was established by SACHRP in October 2006. SOH was established by SACHRP at its July 2009 meeting, and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

Public Comment will be heard on both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business September 30, 2011.

Dated: September 13, 2011.

Jerry Menikoff,

Director, Office for Human Research Protections, Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2011–23863 Filed 9–16–11; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of the Surgeon General of the United States Public Health Service.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that a meeting is scheduled to be held for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the ''Advisory Group''). The meeting will be open to the public. Information about the Advisory Group can be obtained by accessing the following Web site: *http://www.healthcare.gov/center/councils/nphpphc/index.html.*

DATES: The meeting will be held on October 3–4, 2011.

ADDRESSES: Will be announced on the Web site: *http://www.healthcare.gov/center/councils/nphpphc/index.html.*

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave., SW.; Hubert H. Humphrey Building, Room 701H; Washington, DC 20001; 202–205–9517; *prevention.council@hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 10, 2010, the President issued Executive Order 13544 to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. This legislation mandated that the Advisory Group was to be established within the Department of Health and Human Services. The charter for the Advisory Group was established by the Secretary of Health and Human Services on June 23, 2010; the charter was filed with the appropriate Congressional committees and Library of Congress on June 24, 2010. The Advisory Group has been established as a non-discretionary Federal advisory committee.

The Advisory Group has been established to provide recommendations and advice to the National Prevention, Health Promotion and Public Health Council (the ''Council''). The Advisory Group shall provide assistance to the Council in carrying out its mission.

The Advisory Group membership shall consist of not more than 25 non-Federal members to be appointed by the President. The membership shall include a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine. There are currently 16 members of the Advisory Group appointed by the President. This will be the third meeting of the Advisory Group.

Public attendance at the meeting is limited to the space available. Members of the public who wish to attend must register by 12 p.m. EST September 26, 2011. Individuals should register for public attendance at *prevention.council@hhs.gov* by providing your full name and affiliation. Individuals who plan to attend the meeting and need special assistance and/or accommodations, *i.e.,* sign language interpretation or other reasonable accommodations, should notify the designated point of contact for the Advisory Group. The public will have the opportunity to provide comments to the Advisory Group on October 3, 2011; public comment will be limited to 3 minutes per speaker. Registration through the designated contact for the public comment session is also required. Any member of the public who wishes to have printed materials distributed to the Advisory Group for this scheduled meeting should submit material to the designed point of contact no later than 12 p.m. EST September 26, 2011.

Dated: September 8, 2011.

Corinne M. Graffunder,

Acting Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health Office of the Surgeon General.

[FR Doc. 2011–23869 Filed 9–16–11; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice to establish a new system of records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, CMS is establishing a new system of records to support its shared savings programs, the first of which are the Medicare Shared Savings Program and Pioneer ACO Model (collectively referred to as the ACO program). The ACO program implements recent health care reform provisions of the Patient Protection and Affordable Care Act (PPACA), amending the Social Security Act (the Act). The system of records will contain personally identifiable information (PII) about certain individuals who participate in, or whose PII is used to determine eligibility of an Accountable Care Organization (ACO) to participate in, a shared savings program; *i.e.,* Medicare fee-for-service (FFS) beneficiaries, sole proprietor health care ACO participants and ACO suppliers/providers, key leaders and managers of accountable care organizations (ACOs), and contact persons for ACOs. The program and the system of records are more thoroughly described in the Supplementary Information section and System of Records Notice (SORN), below.

DATES: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on September 14, 2011. To ensure that all parties have adequate time in which to comment, the new system, including routine uses, will become effective October 19, 2011. If CMS receives comments that require alterations to this notice, we will publish a revised notice in the **Federal Register**.

ADDRESSES: The public should send comments to: CMS Privacy Officer, Division of Information Security & Privacy Management, Enterprise Architecture and Strategy Group, Office of Information Services, CMS, Room N1–24–08, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., Eastern Time zone.

FOR FURTHER INFORMATION CONTACT: *For Medicare Shared Savings Program:* Rebecca Weiss, Program Analyst, Performance-Based Payment Policy Staff, Center for Medicare, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail-stop: C5–15–12, Baltimore, MD 21244–1850. Office: 410–786–8084, Facsimile: (410) 786–8005, E-mail address: *aco@cms.hhs.gov.*

For Pioneer Aco Model: Alli Chandra, Health Insurance Specialist, Center for Medicare and Medicaid Innovation, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop: S3–13–05, Baltimore, MD 21244–1850. Office Ph: 410–786–1132, Facsimile: (410) 786–0487, E-mail address: *alli.chandra@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: This System of Records Notice (SORN) addresses a new system which HHS is establishing to support CMS shared savings programs created as a result of the Patient Protection and Affordable Care Act (Pub. L. 111–148), the first of which are the Medicare Shared Savings Program and Pioneer ACO Model (ACO program) described in more detail below.

I. Medicare Shared Savings Program

The recently passed health care reform bill, the Affordable Care Act (PPACA) (Pub. L. 111–148), contains provisions that seek to reward quality care and takes steps toward paying for high quality and efficient care. One of these provisions, Section 3022, amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish a shared savings program (SSP) that promotes accountability for a patient population, coordinates items and services under Parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Specifically:

- Section 1899(a)(1) of the Act requires the Secretary to establish the shared savings program no later than January 1, 2012. Section 1899(a)(1) (A) of the Act further provides that, ''groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service (FFS) beneficiaries through an accountable care organization (ACO).''
- Section 1899(a)(1)(B) of the Act provides that ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for ''shared savings.''

The Shared Savings Program is a voluntary program. The statute provides that, to participate in the program, an ACO must ''provide the Secretary with such information regarding the ACO professionals participating in the ACO as the Secretary determines necessary to support the assignment of Medicare fee-for-service beneficiaries to an ACO, the implementation of quality and other reporting requirements * * * and the determination of payments for shared savings.'' The statute requires an ACO to meet certain eligibility criteria including, but not limited to, having ''a formal legal structure that would allow the organization to receive and distribute payments for shared savings,'' having ''in place a leadership and management structure that includes clinical and administrative systems,'' and demonstrating ''to the Secretary that it meets patient-centeredness criteria specific by the Secretary.'' In addition, the ACO must agree to participate for not less than 3 years, have a formal legal structure including primary care providers sufficient for the care of not less than 5000 beneficiaries, and meet others requirements.

The statute defines an ACO as organization of health care providers that agrees to become accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it. The statute states that there are many types of organizational arrangements for eligibility to become an ACO, as determined appropriate by the Secretary.

To qualify for shared savings payments, the ACO must meet specific cost and quality benchmarks. Quality performance standards will be determined by the Secretary and may include measures of clinical processes and outcomes, patient and/or caregiver experience, and utilization measures. An ACO will be eligible to receive a share (a percentage, and any limits, to be determined by the Secretary) of any savings if the actual per capita expenditures of its assigned Medicare beneficiaries are a sufficient percentage below its specified benchmark amount. The benchmark for each ACO will be based on the most recent available three years of per-beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. The benchmark for each ACO will be adjusted for beneficiary characteristics and other factors as determined by the Secretary, and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B.

II. Pioneer ACO Model

Another provision of the Affordable Care Act (PPACA), Section 3021, amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) by adding new section 1899 to the Act to establish the Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center is tasked with development of the Pioneer ACO Model. Under the Pioneer ACO Model, the Innovation Center will engage up to 30 highly experienced provider organizations in testing alternative payment models that include escalating financial accountability and substantial quality/patient experience standards (''outcomes based arrangements''). CMS intends to pursue payment models that (1) *i*nclude escalating levels of financial accountability through successive performance periods during the Participation Agreement; (2) provide a transition to Population-Based Payment by the third performance period, and (3) are projected by CMS to generate Medicare savings by the end of the second performance period.

III. The Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the United States Government collects, maintains, and uses personally identifiable information (PII) in a system of records. A ''system of records'' is a group of any records under the control of a Federal

agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a system of records notice (SORN) identifying and describing each system of records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individual record subjects can exercise their rights under the Privacy Act (*e.g.,* to determine if the system contains information about them).

The Privacy Act permits an agency to disclose information about an individual (PII) without that individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of PII is known as a ''routine use.'' HHS/CMS will only release PII from this system as provided in the ''Routine Uses'' section below. Both identifiable and non-identifiable data may be disclosed under a routine use. HHS/CMS will only disclose the minimum PII necessary to achieve the purpose of the routine use, after determining that:

• The use or disclosure is consistent with the reason that the PII was collected;

• The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

• The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect on and/or risk to the privacy of the individual that additional exposure of the record might bring;

• There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s); and

• The data are valid and reliable.

Additionally, HHS/CMS will require the information recipient to:

• Establish administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record;

• Remove or destroy at the earliest time all individually-identifiable information; and

• Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

SYSTEM NUMBER:
09–70–0598

SYSTEM NAME:

ACO Database System HHS/CMS/CM and HHS/CMS/CMMI.

SECURITY CLASSIFICATION:

Sensitive, unclassified.

SYSTEM LOCATION:

CMS Data Center, 7500 Security Boulevard, North Building, First Floor, Baltimore, Maryland 21244–1850 and at various accountable care organization (ACO) locations and contractor sites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The system will contain personally identifiable information (PII) about the following categories of individuals who participate in, or whose PII is used to determine eligibility of an ACO to participate in, a Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) Medicare shared savings program:

• Medicare fee-for-service (FFS) beneficiaries who receive health care services coordinated and managed by a group of health care providers and suppliers organized to receive shared savings incentive payments, as an accountable care organization (ACO).

• Any providers or suppliers participating in an ACO who are sole proprietorships, for whom certain business-identifying information may therefore constitute personally identifiable information.

• Key leaders and managers of an ACO who provide certain personally identifiable information that is used to determine the ACO's eligibility to participate in the program.

• Any contact persons for an ACO who provide contact information for use in contacting them for information about the ACO.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system may include, but will not necessarily be limited to, the following categories of records, containing PII (or possible PII) data elements such as the following:

• Medicare fee-for-service (FFS) beneficiary claims records, containing the beneficiary's name, gender, Health Insurance Claim Number (HICN) (which could be the beneficiary's Social Security Number), address, date of birth and description of provided services.

• ACO eligibility and contact records, containing the ACO name and address (which could be the home address of a key leader or manager of the ACO); ACO participant or ACO provider/supplier names and addresses (which could include home addresses for any sole proprietor providers/suppliers in the ACO); ACO participant Tax Identification Number (TIN) (which could be a Social Security Number for a sole proprietor ACO participant or ACO provider/supplier in the ACO); National Provider Identifier (NPI) (which is considered PII for an individual provider/supplier); and (for individuals serving as key leaders or managers of an ACO) the individual's name and address (which could be a home address).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Patient Protection and Affordable Care Act (Pub. L. 111–148), which amended Title XVIII of the Social Security Act (the Act) (42 U.S.C. 1395 *et seq.*) to add new section 1899 to the Act to establish a Medicare Shared Savings Program (MSSP); and Section 3021 of the Patient Protection and Affordable Care Act, which amended Title XI of the Social Security Act (the Act) (42 U.S.C. 1301 *et seq.*) to add new section 1115A to the Act to establish the Center for Medicare and Medicaid Innovation.

PURPOSE(S) OF THE SYSTEM:

The system will enable the HHS Centers for Medicare & Medicaid Services (CMS) to administer the ACO program. Relevant HHS personnel, and any CMS contractors, grantees and consultants assisting them, will use personally identifiable information (PII) from this system on a ''need to know'' basis for these purposes:

• Beneficiary claims information and ACO eligibility and contact information will be used to support the regulatory, reimbursement and policy functions of shared savings programs and to combat fraud, waste and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

Any of the PII from this system may be disclosed outside HHS for these routine uses:

1. To obtain assistance from other Federal agencies that help HHS, pursuant to agreements with CMS, to determine the eligibility of ACO applicants to participate in the program. For example, a TIN (which may be a Social Security Number) may be shared with the U.S. Federal Trade Commission (FTC) and the U.S. Department of Justice (DOJ) for purposes of obtaining their assessment of the ACO applicant's market share status.

2. To provide ACOs with information they need to meet requirements and

implement quality and other reporting requirements of the program.

3. To provide information to the U.S. Department of Justice (DOJ), a court, or an adjudicatory body when (a) the Agency or any component thereof, or (b) any employee of the Agency in his or her official capacity, or (c) any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee, or (d) the United State Government, is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation and that the use of such records by the DOJ, court, or adjudicatory body is compatible with the purpose for which the agency collected the records.

4. To assist another Federal agency or an instrumentality of any governmental jurisdiction within or under the control of the United States (including any state or local governmental agency), that administers or that has the authority to investigate potential fraud, waste or abuse in a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste or abuse in such programs.

5. To assist appropriate Federal agencies and HHS contractors that have a need to know the information for the purpose of assisting HHS's efforts to respond to a suspected or confirmed breach of the security or confidentiality of information maintained in this system of records, provided that the information disclosed is relevant and necessary for that assistance.

ADDITIONAL CIRCUMSTANCES AFFECTING DISCLOSURE OF PII ABOUT BENEFICIARIES:

To the extent that the beneficiary claims records in this system contain Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, subparts A and E), disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information'' (see 45 CFR 164–512 (a)(1)). In addition, HHS policy will be to prohibit release even of data not directly identifiable with a particular beneficiary, except pursuant to one of the routine uses or if required by law, if HHS determines there is a possibility that a particular beneficiary can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals could, because of the small size, use this information to deduce the identity of a particular beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM—

STORAGE:

Electronic records will be stored on both tape cartridges (magnetic storage media) and in a in a DB2 and/or Oracle relational database management environment (DASD data storage media). Any hard copies of ACO program-related records containing PII at HHS/CMS, ACO and contractor locations will be kept in hard-copy file folders locked in secure file cabinets during non-duty hours.

RETRIEVABILITY:

Information may be retrieved by any of these personal identifiers: ACO participant TIN (which could be a sole proprietor provider/supplier's Social Security Number), National Provider Identifier (NPI), or beneficiary Health Insurance Claim Number (HICN)) (which may be the beneficiary's Social Security Number).

SAFEGUARDS:

Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

Access to records in the ACO Database System will be limited to CMS personnel, and any contractors, grantees and consultants assisting them, through password security, encryption, firewalls, and secured operating system.

Future system enhancements may allow for ACOs, ACO participants or ACO provider/suppliers, and beneficiaries to be external users of the system, for purposes of viewing and inputting their records in this system. Access controls will ensure that each external user is restricted to viewing only the user's own records, not records pertaining to other users.

Any electronic or hard copies of ACO program-related records containing PII at HHS/CMS, an ACO, and any contractor, grantee or consultant locations will be kept in secure electronic files or in hard-copy file folders locked in secure file cabinets during non-duty hours.

RETENTION AND DISPOSAL:

Records containing PII will be maintained for a period of up to 10 years after entry in the database. Any records that are needed longer, such as to resolve claims and audit exceptions or to prosecute fraud, will be retained until such matters are resolved. Beneficiary claims records are currently subject to a document preservation order and will be preserved indefinitely pending further notice from the U.S. Department of Justice.

SYSTEM MANAGER AND ADDRESS:

Director, Performance-Based Payment Policy Staff, Center for Medicare, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop: C5–15–12, Baltimore, MD 21244–1850; and

Director, Pioneer ACO Model, Center for Medicare and Medicaid Innovation, Centers for Medicare and Medicaid Services, Mailstop: S3–13–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

NOTIFICATION PROCEDURE:

Individuals wishing to know if this system contains records about them should write to one of the system managers and include the pertinent personal identifier used for retrieval of their records (*i.e.,* TIN, NPI or beneficiary Health Insurance Claim Number).

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about them in this system should follow the same instructions indicated under ''Notification Procedure'' and reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a)(2).)

CONTESTING RECORD PROCEDURES:

Individuals seeking to contest the content of information about them in this system should follow the same instructions indicated under ''Notification Procedure.'' The request should reasonably identify the record and specify the information being contested, state the corrective action sought, and provide the reasons for the correction, with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Personally identifiable information in this database is obtained from the

Medicare Beneficiary Database (MBD) (09–70–0536), from the National Claims History File (NCH) (09–70–0558), and from ACOs that provide the information as required to perform the statutory functions of beneficiary assignment, implementation of quality and other reporting requirements, and determination of shared savings.

EXEMPTIONS CLAIMED FOR THIS SYSTEM:

None.

Dated: September 14, 2011.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–23959 Filed 9–15–11; 11:15 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions

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 October 19, 2011.

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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions—(OMB Control Number 0910–New)

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) requires advertisements for prescription drugs to include, among other things, ''such information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.'' Under this authority, FDA has issued regulations to require most prescription drug advertisements to provide a ''true statement of information in brief summary relating to side effects, contraindications, and effectiveness.'' (*§ 202.1(e) (1) (*21 CFR 202.1(e)(1)). To satisfy this requirement, an advertisement that makes claims about a prescription drug must also include a ''fair balance'' of information about the benefits and risks of the advertised product, in terms of both content and presentation (§ 202.1(e)(5)(ii)). In part, *§ 202.1(e)(6)(i) states that* [a]n advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it [c]ontains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in *§ 202.1 ''patients'' means humans and in the case of veterinary drugs, other animals)* safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii)(*b*) and (e)(4)(ii)(*c*) of *§ 202.1)* whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

FDA's current regulations provide a limited exception to the requirement in § 202.1(e)(1), of presenting a true statement of information in brief summary, for ''reminder advertisements'' (''reminder ads'')—advertisements that draw attention to the name of the product but do not make representations about the product's indication(s) or dosage recommendations (§ 202.1(e)(2)(i)). (Certain drugs are not permitted to qualify for the reminder advertisement exemption.) To meet the terms of this exemption, reminders ads must in general be limited to the proprietary and established name of the product and the established name of each active ingredient in the drug product. Reminder ads may also (optionally) contain information about the product's quantitative ingredients, dosage form, quantity, price, and manufacturer, as well as other written, printed, or graphic matter containing no representation or suggestion relating to the product. Further, reminder ads that are intended to provide consumers with information concerning the price charged for a prescription drug product need not meet the terms of § 202.1(e)(2)(i) in order to be exempt from § 202.1(e)(1) if they meet all of the conditions in *§ 200.200 (*21 CFR 200.200). That regulation, in turn, applies to prescription drug reminders ads that are intended solely to provide consumers with information concerning the price charged for a prescription for a particular drug product, and the reminder ad contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use (§ 200.200(a)(1) and (b)).

A topic of ongoing interest for consumer product manufacturers and retailers is the use of consumer-oriented sales promotions such as free trial offers, discounts, money-back guarantees, and rebates. Such promotions are widely used in many product categories, including prescription drugs.

Prior research has demonstrated that the type of promotion offered can affect how consumers respond to the promotion (Refs. 1, 2, and 3). Price incentives [1] may act as cues about product quality. For example, a price incentive may not only act as an economic incentive to buy the product, it may also artificially enhance consumers' perceptions of the product's quality (Ref. 4). In the case that

[1] In this document, we use the terms ''price incentive'' and ''coupon'' interchangeably to refer to the types of promotional offers to be addressed in our study.