encouraged to participate are employers, unions, trade associations, labor associations, professional associations, and foundations. Others are welcome.

This meeting will include updates from NIOSH leadership on NORA as well as updates from approximately half of the Sector Councils on their progress, priorities, and implementation plans to date, including the Agriculture, Forestry and Fishing Sector; Healthcare and Social Assistance Sector; Mining Sector; Mining—Oil and Gas Extraction Sub-Sector; and Transportation, Warehousing and Utilities Sector. After each update, there will be time to discuss partnership opportunities.

Status: The meeting is open to the public, limited only by the capacities of the conference call and conference room facilities. There is limited space available in the meeting room (capacity 34). Therefore, information to allow participation in the meeting through the internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to noracoordinator@cdc.gov containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation by Web meeting (requirements include: computer, internet connection, and telephone, preferably with ''mute'' capability) or in person. An e-mail confirming registration will include the details needed to participate in the Web meeting. Non-US citizens are encouraged to participate in the Web meeting. Non-US citizens registering to attend in person after January 8 will not have time to comply with security procedures.

Background: NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see *http://www.cdc.gov/niosh/nora/about.html.*

Since 2006, NORA has been structured according to industrial sectors. Eight sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008, most of these Councils have posted draft strategic plans for public comment. One has posted its finalized National Sector Agenda after considering comments on its draft. For more information, see the link above and choose ''Sector-based Approach,'' ''NORA Sector Councils,'' ''Sector Agendas'' and ''Comment on Draft Sector Agendas'' from the right-side menu.

Contact Person for Technical Information: Sidney C. Soderholm, Ph.D., NORA Coordinator, e-mail *noracoordinator@cdc.gov*, telephone (202) 245–0665.

Dated: November 19, 2008.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–28152 Filed 11–25–08; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Request for Nominations of Candidates To Serve on the Advisory Committee on Immunization Practices (ACIP)

CDC is soliciting nominations for possible membership on ACIP. This committee provides advice and guidance to the Secretary, Department of Health and Human Services (HHS), and the Director, CDC, regarding the most appropriate application of antigens and related agents for effective communicable disease control in the civilian population. The committee reviews and reports regularly on immunization practices and recommends improvements in the national immunization efforts.

The committee also establishes, reviews, and as appropriate, revises the list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program. Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based upon expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine; knowledge of vaccine development, evaluation, and vaccine delivery; or knowledge about consumer perspectives and/or social and community aspects of immunization programs.

Federal employees will not be considered for membership. Members may be invited to serve for up to four-year terms.

Consideration is given to representation from diverse geographic areas, both genders, ethnic and minority groups, and the disabled. Nominees must be U.S. citizens.

The following information must be submitted for each candidate: name, affiliation, address, telephone number, e-mail address and current curriculum vitae.

Nominations should be accompanied with a letter of recommendation stating the qualifications of the nominee and postmarked by December 15, 2008 to: Antonette Hill, Immunization Service Division, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road, NE., Mailstop E–05, Atlanta, Georgia 30333, Telephone (404) 639–8836.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 18, 2008.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8–28154 Filed 11–25–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0162]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Product Labeling: Medication Guide Requirements

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 (the PRA).

DATES: Fax written comments on the collection of information by December 26, 2008.

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: 202–395–6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0393. Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Prescription Drug Product Labeling: Medication Guide Requirements (OMB Control Number 0910–0393—Extension)

FDA regulations require the distribution of patient labeling, called Medication Guides, for certain prescription human drug and biological products used primarily on an outpatient basis that pose a serious and significant public health concern requiring distribution of FDA-approved patient medication information. These Medication Guides inform patients about the most important information they should know about these products in order to use them safely and effectively. Included is information such as the drug's approved uses, contraindications, adverse drug reactions, and cautions for specific populations, with a focus on why the particular product requires a Medication Guide. These regulations are intended to improve the public health by providing information necessary for patients to use certain medication safely and effectively.

The regulations contain the following reporting requirements that are subject to the PRA. The estimates for the burden hours imposed by the following regulations are listed in the table 1 of this document:

- 21 CFR 208.20—Applicants must submit draft Medication Guides for FDA approval according to the prescribed content and format.
- 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under § 208.26 (21 CFR 208.26).
- 21 CFR 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.
- 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

In the **Federal Register** of March 18, 2008 (73 FR 14471), FDA published a 60-day notice requesting public comment on the information collection provisions. We received the following comments:

(*Comment 1*) The comments said that FDA's estimate of the hourly burden for pharmacists to comply with the Medication Guide requirements is inaccurate, and that pharmacists spend significantly more time determining whether a Medication Guide is required, tracking appropriate Medication Guides from manufacturers or distributors, explaining to the patient what the Medication Guide is, in addition to patient counseling. The comments noted that FDA's estimate that a pharmacist spends 0.0014 hours (5 seconds) to distribute each Medication Guide remains unchanged since the December 1, 1998, final rule entitled ''Prescription Drug Product Labeling; Medication Guide Requirements,'' even though the Medication Guide program has continued to expand (63 FR 66378). The comments said that FDA's estimates are inadequate and fail to consider the operational realities pharmacists now face in complying with the program. The comments said that pharmacy personnel spend tens of thousands of hours obtaining and distributing Medication Guides for each new prescription and all refills for Medication Guide medications.

Response: FDA agrees with the comments. However, the comments did not suggest an alternative burden estimate for Medication Guide distribution by pharmacists. We are increasing the burden estimate for § 208.24(e) to 3 minutes for each Medication Guide distributed by pharmacists. If the commenters believe that this estimate is insufficient, we request comments on why an alternative estimate would be more accurate. We are also increasing to 25 the number of Medication Guides that FDA receives per year under § 208.20.

(*Comment 2*) The comments also said that there are distributor costs to comply with the Medication Guide requirements, and table 1 in the March 18, 2008, **Federal Register** notice omitted § 208.24(c), which provides that ''Each distributor or packer that receives Medication Guides * * * shall provide those Medication Guides * * * to each authorized dispenser to whom it ships a container of drug product.'' The comments said that the burden to distributors and packers to distribute Medication Guides—the process of tracking, sorting, matching, and shipping multiple versions of Medication Guides for multiple products—should be included in the analysis.

Response: FDA agrees with the comments and is willing to include a burden estimate for § 208.24(c). We are requesting comments on specific estimates for this requirement.

(*Comment 3*) The remaining issues raised by the comments in response to the March 18, 2008, **Federal Register** notice are generally the same as the issues raised during FDA's public hearing on the use of Medication Guides to distribute drug risk information to patients (announced in the **Federal Register** of April 9, 2007 (72 FR 17559)) and the same as the comments submitted to that docket. (One commenter also referenced comments previously submitted to FDA in the ''June 2006 White Paper on *Patient Safety Implications on Implementation of the Current FDA-Mandated Medication Guide Program*''). On July 2, 2007, FDA posted a ''Summary of Public Hearing on FDA's Use of Medication Guides to Distribute Drug Risk Information to Patients'' at *http://www.fda.gov/cder/meeting/SummaryPublicHearingMedicationGuides.htm*. The issues raised in conjunction with the public hearing, as well as the comments summarized below, are still under consideration at FDA, and we have not yet decided what actions we will take in response to suggestions to modify the Medication Guide program.

The following is a summary of the comments received on the March 18, 2008, notice; these comments do not pertain to the specific burden estimates, but were taken into consideration by FDA.

(*Comment 4*) The comments said that despite stating in the Medication Guide final rule that FDA will use Medication Guides sparingly, the agency continues to add new Medication Guides for drugs in a manner inconsistent with its

original intent. The comments said that FDA intended Medication Guides to be used only when a drug posed very serious or significant side effects, and that it anticipated the program to be limited to a small number of products, and not more than 5 to 10 products per year. The comments said that by 2004, about 20 products required Medication Guides, and that starting in 2005, FDA began requiring Medication Guides for entire medication classes, which have grown to include antidepressants, nonsteroidal anti-inflammatory drugs, and attention deficit hyperactivity disorder and sleep disorder drugs. The comments said that today almost 300 million prescriptions per year for over 10,000 separate drug products are subject to the Medication Guide requirement, and pharmacists are dispensing Medication Guides for substantially more drugs than originally estimated. The comments said that this has created significant burdens for pharmacists.

(*Comment 5*) The comments said that there is no evidence that a Medication Guide is a good vehicle for risk communication, and FDA has not provided evidence that the program is valuable to patients or improves the safe and effective use of prescription drugs. The comments said that given the amount of information patients are likely to receive with their prescriptions, they face a tremendous challenge in actually reading each piece of information. As a result, the comments said, many patients are likely to not read any material provided to them. Those patients that desire to gain additional information about their therapy but are unable to read each document are placed in a position of having to decide which document distributed to them is more important than the other. The comments said that FDA should first evaluate whether patients actually read the Medication Guides distributed to them, and then assess whether the information contained in a Medication Guide is easily understood by patients. The comments said that many patients are likely to find the information difficult to understand or confusing, and that many patients, especially older and disabled patients, have cognitive impairments that may pose tremendous challenges in understanding information contained in a Medication Guide. The comments also asked whether the information contained in the Medication Guide is already available to patients. For example, the comments said that pharmacists provide counseling on the safe and effective use of medication to their patients at the time of dispensing, and are able to translate highly complex information about a drug's characteristics, use parameters, side-effects and abuse potential. The comments said this counseling by pharmacists, coupled with other information already distributed to patients, such as consumer medication information and the patient package insert or the patient information sheet, raises questions about the need for the Medication Guide program. The comments also said that FDA has not made sufficient data available to the public to support the position that the Medication Guide program is important to communicate risk, and FDA should release all data from its surveys and studies for review and comment by health care provider groups. The comments said that this data will help generate a more accurate estimate of the burden imposed on the public as a result of the Medication Guide program.

(*Comment 6*) The comments said that pharmacists face difficulties in obtaining Medication Guides. The comments said that some Medication Guides are included with the product itself in the package insert, some are provided in tear-off sheets, and some are available electronically. The comments said that the lack of a standardized delivery model complicates efforts to operationally streamline dispenser and distribution systems for duplicating and providing Medication Guides. In addition, pharmacists at times need to call a toll-free number to order hard copies of the Medication Guides for distribution. The comments said that FDA should establish standards for manufacturer distribution of medication guides and establish a single toll-free number or Internet site for pharmacies to use to obtain Medication Guides.

(*Comment 7*) The comments said that FDA should waive certain Medication Guide formatting requirements to permit pharmacies to print Medication Guides through existing pharmacy computer systems. The comments said that permitting pharmacies to print Medication Guides would enhance their distribution and will free pharmacists' time to use for patient counseling and care. The comments also said FDA should permit pharmacies to e-mail Medication Guides to their patients.

(*Comment 8*) The comments said that a single, uniform Medication Guide should be used for all brand and generic versions of the same drug, or for drugs within the same therapeutic class, with similar risk warnings, and that each brand and generic manufacturer of the same drug or the same class of drug should not have to produce its own Medication Guide. The comments said that for medications that have unique and rare side effects that are not shared with the other drugs in the same class, FDA should consider having a class Medication Guide that specifically lists per paragraph each drug in the class while highlighting risk information that is unique to certain medications within that class.

(*Comment 9*) The comments said that Medication Guides should only be required the first time a prescription is filled, and thereafter only when requested by a patient for that prescription's refill.

(*Comment 10*) The comments said to eliminate duplication and enhance the usefulness of patient information, a single, manufacturer-produced, patient-oriented FDA-approved Medication Information Document should be developed for each drug that currently requires a Medication Guide. This single document could combine consumer medication information and Medication Guide information. The comments said they are willing to work with FDA and other interested stakeholders in designing and implementing such a program. Alternatively, the comments said that FDA should standardize the information that must be included in the Medication Guide and require a consistent format, look, and feel to Medication Guide information.

(*Comment 11*) The comments said that physicians and other providers should give the Medication Guide directly to the patient at the time the prescription is written. The comments said the physician is in the best position to discuss not only the possible risks associated with the medication but to also discuss alternative therapies if necessary. The comments also said that FDA should consider ways that prescribers could be better informed about medications that require Medication Guides.

(*Comment 12*) The comments said that the Medication Guide requirements were imposed on distribution and dispensing entities that were neither prepared nor operationally structured (for example, lack of space, staff, and equipment) to prepare and provide for their dissemination.

Based on the comments in ''*Comment* (1)'' of this document, FDA has revised the estimated annual reporting burden as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
208.20	25	1	25	320	8,000
208.24(e)	59,000	5,000	295,000,000	0.05	14,750,000
208.26(a)	1	1	1	4	4
314.70 (b)(3)(ii) and 601.12(f)	5	1	5	72	360
Total					14,758,364

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

Dated: November 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28064 Filed 11–25–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0595]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on a 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 a study examining the impact on consumer comprehension of inclusion of a toll-free number to report side effects in direct-to-consumer (DTC) prescription drug television advertisements.

DATES: Submit written or electronic comments on the collection of information by January 26, 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, 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.

Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs

The Federal Food, Drug, and Cosmetic Act (the act) requires that manufacturers, packers, and distributors (sponsors) who advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. 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.

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110–85). Title IX of FDAAA amends section 502(n) of the act (21 U.S.C. 352) by requiring printed DTC advertisements for prescription drug products to include the following statement printed in conspicuous text: ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch*, or call 1–800–FDA–1088.'' Title IX of FDAAA also requires the Secretary of Health and Human Services (the Secretary), in consultation with the Risk Communication Advisory Committee (RCAC), to conduct a study not later than 6 months after the date of enactment of FDAAA to determine if this statement is appropriate for inclusion in DTC television advertisements for prescription drug products. As part of this study, the Secretary shall consider whether the information in the statement described previously in this paragraph would