Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. BSC meetings are held annually or biannually.

Dated: May 15, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. E9–12204 Filed 5–26–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; REDS–II Donor Iron Status Evaluation (RISE) Study

Summary: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 9, 2009, pages 10057–10058 and allowed 60-days for public comment. No comments were received in response to this notice. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a current valid OMB control number.

Proposed Collection

Title: REDS–II Donor Iron Status Evaluation (RISE) Study. *Type of Information Collection Request:* Revision of a currently approved collection. OMB control #0925–0581. *Expiration Date:* 05/31/2009. *Need and Use of Information Collection:* Although the overall health significance of iron depletion in blood donors is uncertain, iron depletion leading to iron deficient erythropoiesis and lowered hemoglobin levels results in donor deferral and, occasionally, in mild iron deficiency anemia. Hemoglobin deferrals represent more than half of all donor deferral, deferring 16% of women. The RISE Study is a longitudinal study of iron status in two cohorts of blood donors: a first time/reactivated donor cohort in which baseline iron and hemoglobin status can be assessed without the influence of previous donations, and a frequent donor cohort, where the cumulative effect of additional frequent blood donations can be assessed. Each cohort's donors will donate blood and provide evaluation samples during the study period.

The primary goal of the study is to evaluate the effects of blood donation intensity on iron and hemoglobin status and assess how these are modified as a function of baseline iron/hemoglobin measures, demographic factors, and reproductive and behavioral factors. Hemoglobin levels, a panel of iron protein, red cell and reticulocyte indices will be measured at baseline and at a final follow-up visit 15–24 months after the baseline visit. A DNA sample will be obtained once at the baseline visit to assess three key iron protein polymorphisms. Donors will also complete a self-administered survey assessing past blood donation, smoking history, use of vitamin/mineral supplements, iron supplements, aspirin, frequency of heme rich food intake, and, for females, menstrual status and pregnancy history at these two time points. This study aims to identify the optimal laboratory measures that would predict the development of iron depletion, hemoglobin deferral, and/or iron deficient hemoglobin deferral in active whole blood and double red cell donors at subsequent blood donations. The data collected will help evaluate hemoglobin distributions in the blood donor population (eligible and deferred donors) and compare them with NHANES data. Other secondary objectives include elucidating key genetic influences on hemoglobin levels and iron status in a donor population as a function of donation history; and establishing a serum and DNA archive to evaluate the potential utility of future iron studies and genetic polymorphisms.

This study will develop better predictive models for iron depletion and hemoglobin deferral (with or without iron deficiency) in blood donors; allow for the development of improved donor screening strategies and open the possibility for customized donation frequency guidelines for individuals or classes of donors; provide important baseline information for the design of targeted iron supplementation strategies in blood donors, and improved counseling messages to blood donors regarding diet or supplements; and by elucidating the effect of genetic iron protein polymorphisms on the development of iron depletion, enhance the understanding of the role of these proteins in states of iron stress, using frequent blood donation as a model.

This request for modification is to add eleven questions to the RISE study final visit questionnaire that will include questions about Restless Leg Syndrome (RLS) and pica, two disorders associated with iron deficiency. RLS is a neurologic movement disorder in which patients complain of crawling, aching or indescribable feelings in their legs or just have the need to move. Pica is an eating disorder defined as compulsive ingestion of non-food substances. Blood donation results in the removal of 200–250 mg of iron from the donor. It is well established that repeated blood donation can produce iron deficiency, yet the prevalence of RLS and pica among blood donors is unknown. The REDS–II RISE study subjects are an ideal study population for the investigation of RLS and pica in blood donors. About 2,400 subjects with variable donation intensity (*e.g.* frequency with which a person donates blood) are currently enrolled in the RISE Study. The iron status of all of these subjects is well characterized, including measurement of plasma ferritin and soluble transferrin receptor along with hemoglobin/hematocrit. These laboratory values allow each subject to be defined as 1) iron replete, 2) iron deficient without anemia or 3) iron deficiency anemia. The responses to these questions will be correlated with the laboratory test values to determine the relationship between blood donation and the development of RLS and pica and will establish its prevalence in these populations.

Frequency of Response: Twice. *Affected Public:* Individuals. *Type of Respondents:* Adult blood donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* Baseline visit: 2,340, Follow up visit: 1,530; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* Baseline Visit: 0.37, Follow up Visit: 0.25; and *Estimated Total Annual Burden Hours Requested:* Baseline visit: 866, Follow up Visit: 383. The annualized cost to respondents is estimated at: Baseline

Visit: $15,588, Follow up Visit: $6,894 (based on $18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Blood donors at Baseline Visit	2,340	1	0.37	866
Blood donors at Follow-up Visit	1,530	1	0.25	383
Total				1,249

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Suite 361, 6700 Rockledge Drive, Bethesda, MD 20892, or call non-toll free number 301–435–0075, or e-mail your request, including your address to *nemog@nih.gov*.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received *within 30 days* of the date of this publication.

Dated: May 15, 2009.

George Nemo,

Project Officer, NHLBI.

[FR Doc. E9–12210 Filed 5–26–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0253]

Draft Guidance for Industry on Presenting Risk Information in Prescription Drug and Medical Device Promotion; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Presenting Risk Information in Prescription Drug and Medical Device Promotion.'' This guidance responds to stakeholder requests for specific guidance on how FDA evaluates prescription drug and device promotional pieces to determine whether they adequately present risk information. The guidance describes and discusses the factors FDA considers when evaluating prescription drug advertisements (ads), restricted device ads, and prescription drug and device promotional labeling for their compliance with the Federal Food, Drug, and Cosmetic Act (the act) and relevant regulations. The guidance gives examples to illustrate FDA's thinking on these factors and is intended to help regulated industry gain a better understanding of what they should consider as they develop the content and format of their promotional communications.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by August 25, 2009. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding human prescription drugs*: Kristin Davis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Ele Ibarra-Pratt, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852–1448, 301–827–3028.

Regarding medical device products: Ann Simoneau, Center for Devices and Radiological Health (HFZ–302), 2094 Gaither Rd., Rockville, MD 20850, 240–276–0100.

Regarding prescription animal drug products: Martine Hartogensis, Center for Veterinary Medicine (HFV–216), 7519 Standish Pl., Rockville, MD 20855, 240–453–6833.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Presenting Risk Information in