

Request for Comment

Comments are invited on:

a. Whether the information collection is necessary for the proper performance of the agencies' functions, including whether the information has practical utility;

b. The accuracy of the agencies' estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or start up costs and costs of operation, maintenance, and purchase of services to provide information.

Comments submitted in response to this notice will be shared among the agencies. All comments will become a matter of public record. Written comments should address the accuracy of the burden estimate and ways to minimize burden including the use of automated collection techniques or the use of other forms of information technology as well as other relevant aspects of the information collection request.

Board of Governors of the Federal Reserve System, May 21, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

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available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 22, 2009.

Federal Reserve Bank of Chicago

(Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. *Hantz Holdings, Inc.*, Southfield, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of Davison State Bank, Davison, Michigan.

In connection with this application, Applicant also has applied to acquire Tranex Financial, Inc., Southfield, Michigan, and thereby engage in making and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, May 21, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

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otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated.

The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 22, 2009.

A. Federal Reserve Bank of Atlanta

(Steve Foley, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. *First America Holdings Corporation*, Osprey, Florida; to acquire 100 percent of the voting shares of MRCB Holdings, Inc., Palmetto, Florida, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, May 21, 2009.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Toxicology Program (NTP); Office of Liaison, Policy and Review Meeting of the NTP Board of Scientific Counselors**

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

ACTION: Meeting announcement and request for comments.

SUMMARY: Pursuant to Public Law 92-463, notice is hereby given of a meeting of the NTP Board of Scientific Counselors (BSC). The BSC is a federally chartered, external advisory group composed of scientists from the public and private sectors that provides primary scientific oversight to the NTP Director and evaluates the scientific merit of the NTP's intramural and collaborative programs.

DATES: The BSC meeting will be held on July 23-24, 2009. The deadline for submission of written comments is July 9, 2009, and for pre-registration to attend the meeting, including registering

FEDERAL RESERVE SYSTEM**Formations of, Acquisitions by, and Mergers of Bank Holding Companies**

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications also will be

FEDERAL RESERVE SYSTEM**Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities**

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless

to present oral comments, is July 16, 2009. Persons needing interpreting services in order to attend should contact 301-402-8180 (voice) or 301-435-1908 (TTY). For other accommodations while on the NIEHS campus, contact 919-541-2475 or e-mail niehsoeeo@niehs.nih.gov. Requests should be made at least 7 days in advance of the event.

ADDRESSES: The BSC meeting will be held in the Rodbell Auditorium, Rall Building, at the NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. Public comments on all agenda topics and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the BSC, NTP Office of Liaison, Policy and Review, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709; *telephone:* 919-541-4253; *fax:* 919-541-0295; or *e-mail:* shane@niehs.nih.gov. *Courier address:* NIEHS, 530 Davis Drive, Room K 2138, Research Triangle Park, NC 27713.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Shane (*telephone:* 919-541-4253 or *e-mail:* shane@niehs.nih.gov).

SUPPLEMENTARY INFORMATION:

Preliminary Agenda Topics and Availability of Meeting Materials

- Update of NTP Activities.
- Report of the Technical Reports Review Subcommittee Meeting held February 25, 2009.
- NTP Testing Program: Nominations and Proposed Research Projects on alkylanilines, *p*-chlorobenzotrifluoride, deoxynivalenol, Dong quai, indium tin oxide, and tris(4-chlorophenyl)methane and tris(4-chlorophenyl)methanol.
- Contract Concept Review: Investigative ADME Studies of Toxicants in NTP Animal Model Systems.
- Contract Concept Review: Toxicology and Carcinogenicity Studies.

- Contract Concept Review: Report on Carcinogens Support Contract.

- Interagency Agreements with Food and Drug Administration/National Center for Toxicological Research and Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health.

The preliminary agenda, roster of BSC members, draft NTP research concepts, public comments, and any additional information, when available, will be posted on the BSC meeting Web site (<http://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Executive Secretary for the BSC (see **ADDRESSES** above). Any updates to the agenda will also be posted to this site. Following the meeting, summary minutes will be prepared and made available on the NTP meeting Web site.

NTP Testing Program: Nominations and Proposed Research Projects

The NTP actively seeks to identify and select for study chemicals and other substances for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal, open nomination and selection process. Substances considered appropriate for study generally fall into two broad, yet overlapping categories: (1) Substances judged to have high concern as possible public health hazards based on the extent of human exposure and/or suspicion of toxicity and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, *e.g.*, by facilitating cross-species extrapolation or evaluating dose-response relationships. Nominations are subject to a multi-step, formal process of review before selections for testing are made and toxicological studies are designed and implemented. The nomination review and selection process is accomplished through the

participation of representatives from the NIEHS, other federal agencies represented on the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the BSC, the NTP Executive Committee—the NTP federal interagency policy body, and the public. The nomination review and selection process is described in further detail on the NTP Web site (<http://ntp.niehs.nih.gov/>, select “Nominations to the Testing Program”).

Table 1 lists new nominations to be reviewed at the BSC meeting. Background documents for each nomination are available on the NTP Web site <http://ntp.niehs.nih.gov/go/nom>. The NTP invites interested parties to submit written comments, provide supplementary information, or present oral comments at the BSC meeting on the nominated substances and preliminary study recommendations (see “Request for Comments” below). The NTP welcomes toxicology study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is interested in identifying appropriate animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and high-throughput *in vitro* test methods, and as such, solicits comments regarding the use of specific *in vivo* and *in vitro* experimental approaches to address questions relevant to the nominated substances and issues under consideration. Although the deadline for submission of written comments to be considered at the BSC meeting is July 9, 2009 (see “Request for Comments” below), the NTP welcomes comments or additional information on these study nominations at any time.

TABLE 1—TESTING RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES

Substance [CAS No.]	Nomination source	Nomination rationale	Preliminary study recommendations
Alkylanilines 2-Ethylaniline [578-54-1] 3-Ethylaniline [587-02-0] 3,5-Dimethylaniline [108-69-0]	National Institute of Environmental Health Sciences ¹ .	Potential for human exposure from a variety of industrial and ambient sources; suspicion of toxicity based on chemical structure; insufficient data to characterize toxicity of this ani- line subclass.	Initial toxicological characteriza- tion.
<i>p</i> -Chlorobenzotrifluoride [98-56-6]	Kowa American Corp.	High production volume; increas- ing industrial and potential con- sumer use; lack of workplace exposure standards; lack of chronic toxicity data.	Comprehensive toxicological char- acterization including develop- mental and reproductive toxicity and chronic toxicity/carcino- genicity studies.

TABLE 1—TESTING RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES—Continued

Substance [CAS No.]	Nomination source	Nomination rationale	Preliminary study recommendations
Deoxynivalenol [51481–10–8]	NIEHS	Widespread environmental occurrence and potential for human exposure through consumption of contaminated foods; demonstrated toxicological activity; lack of definitive carcinogenicity and reproductive toxicity studies.	Comprehensive toxicological characterization including reproductive toxicity and chronic toxicity/carcinogenicity studies.
Dong quai (<i>Angelica sinensis</i> root [308068–61–3] and extract [299184–76–2]).	Private Individual	Widespread use as a dietary supplement; suspicion of toxicity based on estrogenic activity and chemical structure; lack of adequate toxicity data.	Comprehensive toxicological characterization including photo-toxicity studies.
Indium tin oxide [50926–11–9]	NIEHS	Increasing production and use; documented pulmonary effects in exposed workers; suspicion of toxicity based on chemical structure; lack of adequate toxicity data.	Comprehensive toxicological characterization.
Tris(4-chlorophenyl)methane [27575–78–6] and Tris(4-chlorophenyl)methanol [3010–80–8].	NIEHS	Widespread occurrence and persistence in the environment; suspicion of toxicity based on anti-androgenic activity; lack of adequate toxicity data.	Initial toxicological characterization.

¹ National Institute of Environmental Health Sciences (NIEHS)

² The terms “initial” and “comprehensive toxicological characterization” in this table refer to the approximate scope of a research program to address toxicological data needs. The types of toxicological studies that would be considered by NTP staff during the conceptualization and design of a research program are:

- Initial toxicological characterization: biomolecular screening, *in vitro* mechanistic, *in vitro* and *in vivo* genotoxicity, absorption, disposition, metabolism, and elimination, and short-term repeat dose (2–4 weeks) *in vivo* studies.

- Comprehensive toxicological characterization: all of the aforementioned plus subchronic toxicity (13–26 weeks), chronic toxicity (1–2 years), carcinogenicity in conventional or genetically modified rodent models, organ systems toxicity (immunotoxicity, reproductive and developmental toxicity, neurotoxicity), *in vivo* mechanistic, toxicokinetics, and other special studies as appropriate (e.g., chemistry, toxicogenomics, phototoxicity).

To facilitate review of proposed research projects by the BSC and the public, NTP staff developed a draft research concept document for each nomination recommended for study. A research concept is a brief document outlining the nomination or study rationale, and the significance, study approach, and expected outcome of a proposed research program tailored for each nomination. The purpose of these research concepts is to outline the general elements of a program of study that would address the specific issues that prompted the nomination, but also encompass studies that may address larger public health issues or topics in toxicology that could be addressed appropriately through studies on the nominated substance(s). Draft research concepts for the new nominations listed in Table 1 will be available on the BSC meeting page (<http://ntp.niehs.nih.gov/go/165>) by June 8, 2009.

Attendance and Registration

The meeting is scheduled for July 23–24, 2009, beginning at 8:30 a.m. on each day and continuing to 5 p.m. on July 23 and on July 24 until adjournment. The meeting is open to the public with

attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the BSC meeting Web site (<http://ntp.niehs.nih.gov/go/165>) by July 16, 2009, to facilitate planning for the meeting. The NTP is making plans to videocast the meeting through the Internet at <http://www.niehs.nih.gov/news/video/live>.

Request for Comments

Written comments submitted in response to this notice should be received by July 9, 2009. Comments will be posted on the BSC meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), phone, e-mail, and sponsoring organization (if any) with the document.

Time will be allotted during the meeting for the public to present oral comments to the BSC on the agenda topics. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to

10 minutes at the discretion of the BSC chair. Persons wishing to present oral comments are encouraged to pre-register on the NTP meeting Web site by July 16. Registration for oral comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the BSC (see **ADDRESSES** above) by July 16, 2009. Written statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution to the BSC and NIEHS/NTP staff and to supplement the record.

Background Information on the NTP Board of Scientific Counselors

The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the overall program and its centers.

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]

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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