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
170.39	6	1	6	48	288

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

The above annual reporting estimate is based on information received from representatives of the food packaging and processing industries and on agency records. In the past, FDA has typically received 60 threshold of regulation exemption requests per year.

However, it is estimated that up to 90 percent of the requests that would have previously been submitted under § 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the act.

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32784 Filed 12–22–00; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request; Evaluation of a Public Education Campaign on Drinking During Pregnancy

SUMMARY: Under the provisions of Section 3507(a)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on September 18, 2000, page 56316 and allowed 60-days for public comment. No public comments were received. 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 currently valid OMB control number.

Proposed Collection

Title: Evaluation of a Public Education Campaign on Drinking During Pregnancy.

Type of Information Collection Request: New Collection.

Need and Use of Information Collection: The evaluation is being conducted to determine whether the public education campaign on alcohol consumption during pregnancy raises awareness and attentiveness to the problems of drinking during pregnancy among the target audience of African American women ages 21–29 residing in Washington, DC. The public education campaign, funded by NIAAA, is in response to a need for increased awareness among African American women of childbearing age about the consequences of drinking during pregnancy, the most severe of which is Fetal Alcohol Syndrome (FAS). The two-year campaign will be launched during the spring of 2001, and will serve as a pilot program for possible replication in other communities across the country.

The information from the evaluation of the public information campaign is to be used by NIAAA to inform policy and practice related to public education efforts targeted toward preventing drinking during pregnancy. The collection of information will take place at two points (pretest and posttest): (1) In the spring, 2001, prior to commencement of the public education campaign, to gather baseline data on knowledge of the effects of drinking during pregnancy; and (2) in the winter, 2003, immediately following the conclusion of the public education campaign, to determine whether the message to the target audience had its intended effect. The data collected will be analyzed to: (1) Increase understanding about the extent of African American women's knowledge of the risks of drinking during pregnancy; (2) evaluate whether a public education campaign targeted towards African American women is effective in increasing awareness; and (3) assess the campaign's strengths and weaknesses in order to provide guidance to other similar public education campaigns.

The public education campaign and evaluation are new efforts that will continue for approximately two years.

Frequency of Response: Once per respondent. Potential respondents will be screened to avoid including individuals in both the pre- and post-test invervals as well as including individuals multiple times in a single test interval.

Affected Public: Individuals.

Type of Respondents: Adults. The annual reporting burden is as follows:

Estimated Number of Respondents: 400 at each of the two data collection points, for a total of 800 respondents.

Estimated Number of Responses per Respondent: One response per respondent.

Average Burden Hours per Response: 5-minute response per individual, for a total respondent burden of 4045 minutes, including pilot test responses.

Estimated Total Annual Burden Hours Requested: 67.4 hours. There are no Costs to Respondents to report. There are no Capital Costs to report. There are no Operating or Maintenance costs to report.

Request for Comments

Written comments and suggestions from the public and affected agencies are invited on the following points: (1) Whether the data collection 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 assumptions; (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 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: Ms. Diane Miller, Scientific Communications Branch, Office of Scientific Affairs, NIAAA, NIH, Willco Building, Suite 409, 6000 Executive Boulevard, Rockville, MD, 20892–7003 or e-mail your request, including your address to: dmiller@willco.niaaa.nih.gov. Ms. Miller can be contacted by telephone at 301–443–3860.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before January 25, 2001.

Dated: December 15, 2000.

Stephen Long,

Executive Officer, NIAAA.

[FR Doc. 00–32817 Filed 12–22–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Dombrock Blood Typing

Jeffery L. Miller, Alexander Gubin, Marion E. Reid (NIDDK)

[DHHS Reference No. E–185–00/0 filed 23 Sep 2000]

Licensing Contact: John Rambosek; 301/496–7056 ext. 270; email: rambosej@od.nih.gov.

The Dombrock blood group was first discovered in 1965. It is comprised of five alleles: two common alleles, Do(a+) and Do(b+), and three very rare alleles Gy(a), Hy, and Jo(a) which are essentially different null alleles. The Dombrock blood group system has been estimated to be the fifth most useful blood group marker in Caucasians. Blood typing for this blood group is hard to do, since there is a limited amount of antibodies, and the antigens are tricky to work with. This invention discloses the gene and polymorphisms of that gene that result in the Dombrock blood group antigenicity. Thus this invention provides for the first time a method for reliably typing the human blood supply for the Dombrock blood group antigenicity. The genetic information may also be used to generate antigen-specific antibodies for blood typing. The primary use for the technology is to improve blood typing practices through molecular means and thereby prevent clinical problems (transfusion reactions, etc.) associated with improperly mismatched blood.

Microbial Identification Databases

Jon G. Wilkes, Fatemeh Rafii, Katherine L. Glover, Manuel Holcomb, Cao M. Xiaoxi, John B. Sutherland (FDA)

[DHHS Reference No. E–169–00/0 filed 10 Oct 2000]

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov.

The invention is a method for assembling a coherent database containing an essentially unlimited number of pyrolysis mass spectra to enable rapid chemotaxonomy of unknown microbial samples. The invention corrects for short and long-term drift of microbial pyrolysis mass spectra by using spectra of similar microbes as internal standards. The invention provides for the first time a practical way to assemble a coherent database containing an essentially unlimited number of pyrolysis mass spectra, where one or more is representative of each relevant strain, and representative of additional strains as they are added to the pool of microbial agents. Microorganisms can be identified using the invention from their fingerprint spectra regardless of the growth medium used to culture the bacteria. This is a result of the discovery that corrections made to the fingerprint spectrum of one type of bacterium to compensate for changes in growth medium may be applied successfully to metabolically similar bacteria. Fingerprint spectra to which the method of the invention may be applied include mass spectra, infrared spectra, chromatograms, NMR spectra and ion-mobility spectra. The present invention is especially useful for the rapid identification of microorganisms, including human pathogens.

Quantifying Gene Relatedness via Nonlinear Prediction of Gene Expression Levels

Dougherty et al. (NHGRI)

[Serial No. 09/595,580 filed 15 Jun 2000]

Licensing Contact: Dale Berkley; 301/496–7735 ext. 223; e-mail: berkleyd@od.nih.gov.

This invention relates to a new way to analyze the function of a newly identified gene. Working together, the genes within a genomic system constitute a control system for modulating gene expression activity and protein production. Regulation within this control system depends on multivariate relations among genes. Therefore, a key window into understanding genomic activity is to quantify the manner in which the expression profile among a set of genes can be used to predict the expression levels of other genes. This invention provides the experimental, statistical, and computational basis for nonlinear and linear multivariate prediction and co-determination among gene expression levels, and it is applied in the context of cDNA microarrays. Using these measures of multi-gene interactivity, it is possible to infer genomic regulatory mechanisms and thereby identify the manner in which genetic malfunction contributes to cancer and developmental anomalies.

Dated: December 14, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00–32814 Filed 12–22–00; 8:45 am]

BILLING CODE 4140–01–P