reducing the burden associated with compliance.

In response to the statutory requirement in section 4005(c), EPA developed 40 CFR part 239, commonly referred to as the State Implementation Rule (SIR). The SIR describes the State application and EPA review procedures and defines the elements of an adequate State permit program.

The collection of information from the State during the permit program adequacy determination process allows EPA to evaluate whether a program for which approval is requested is appropriate in structure and authority to ensure owner or operator compliance with the revised federal criteria. The SIR does not require the use of a particular application form. Section 239.3 of the SIR, however, requires that all State applications contain the following five components:

(1) A transmittal letter requesting permit program approval.

(2) A narrative description of the State permit program, including a demonstration that the State's standards for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste are technically comparable to the part 257, subpart B criteria and/or that its MSWLF standards are technically comparable to the part 258 criteria.

(3) A legal certification demonstrating that the State has the authority to carry out the program.

(4) Copies of State laws, regulations, and guidance that the State believes demonstrate program adequacy.

(5) Copies of relevant State-tribal agreements if the State has negotiated with a tribe for the implementation of a permit program for non-municipal, non-hazardous waste disposal units that receive CESQG hazardous waste and/or MSWLFs on tribal lands.

The EPA Administrator has delegated the authority to make determinations of adequacy, as contained in the statute, to the EPA Regional Administrator. The appropriate EPA Regional Office, therefore, will use the information provided by each State to determine whether the State's permit program satisfies the statutory test reflected in the requirements of 40 CFR part 239. In all cases, the information will be analyzed to determine the adequacy of the State's permit program for ensuring compliance with the federal revised criteria.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

The EPA would like to solicit comments to:

(i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(ii) Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(iii) Enhance the quality, utility, and clarity of the information to be collected; and

(iv) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden Statement: Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

The total burden for States, territories, and the EPA regions for the collection and evaluation of the information under this ICR is estimated to be about 7,210 hours and $352,800. The estimated burden includes time for reviewing instructions, searching existing data sources, gathering and maintaining necessary data, and completing and reviewing the collection of information. The ICR supporting statement describes the assumptions and information sources used to develop the burden estimate for this ICR. For a copy of the supporting statement, contact Craig Dufficy at (703) 308–9037, or e-mail *dufficy.craig@epa.gov.* Requests should reference the document title, ''Supporting Statement for EPA Information Collection Request #1608.04''. There is no recordkeeping burden associated with this ICR.

Dated: December 20, 2004.

Matt Hale,

Director, Office of Solid Waste.

[FR Doc. 05–102 Filed 1–3–05; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may obtain copies of agreements by contacting the Commission's Office of Agreements at 202–523–5793 or via e-mail at *tradeanalysis@fmc.gov.* Interested parties may submit comments on an agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days of the date this notice appears in the **Federal Register**.

Agreement No.: 011893.

Title: Westwood/Star Sailing and Space Charter Agreement.

Parties: Westwood Shipping Lines, Inc. and Star Shipping A.S.

Filing Party: Pamela J. Auerbach, Esq.; Kirkland & Ellis LLP; 655 Fifteenth Street, NW., Washington, DC 20005.

Synopsis: The proposed agreement would authorize the parties to operate a service and share space in the trade between the U.S. and Canadian Pacific Coasts and ports in Japan, Korea, and China.

By Order of the Federal Maritime Commission.

Dated: December 29, 2004.

Karen V. Gregory,

Assistant Secretary.

[FR Doc. 05–99 Filed 1–3–05; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Early Hearing Detection and Intervention (EHDI) Tracking, Surveillance, and Integration

Announcement Type: New.

Funding Opportunity Number: RFA 05028.

Catalog of Federal Domestic Assistance Number: The Catalog of Federal Domestic Assistance number is 93.283.

DATES:

Letter of Intent Deadline (LOI): February 3, 2005.

Application Deadline: March 7, 2005.

I. Funding Opportunity Description

Authority: This program is authorized under section 317(k)(2) and 317(C) of the Public Health Service Act, [42 U.S.C. sections 247b(k)(2) and 247b–4], as amended.

Purpose: Currently, all States and many territories have established early hearing detection and intervention programs and 37 states, plus the District of Columbia and Puerto Rico, have passed legislation related to universal newborn hearing screening. The purpose of the program is to (1) develop or enhance a sustainable state-based EHDI tracking and surveillance system capable of accurately ascertaining the disposition of every occurrent birth for each step throughout the EHDI process, and (2) integrate the EHDI system with other State/territorial screening, tracking, and surveillance programs that identify children with special health care needs. Data from the integrated EHDI system will enable State/territories and the Directors of Speech and Hearing Programs in State Health and Welfare Agencies (DSHPSHWA) to report accurate data for Healthy People 2010 Objective 28–11, and to assess progress on the EHDI National Goals.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center on Birth Defects and Disabilities: Prevent birth defects and developmental disabilities and improve the health and quality of life of Americans with disabilities.

This announcement is only for non-research activities supported by CDC/ATSDR. If research is proposed, the application will not be reviewed. For the definition of research, please see the CDC Web site at the following Internet address: *http://www.cdc.gov/od/ads/opspoll1.htm*.

Activities: Awardee activities for this program are as follows:

• Establish or improve a State/territorial population based surveillance and data tracking system to minimize infants lost to follow-up by monitoring the status and progress of every infant through the three components of the EHDI process including the specific results of screening, audiological diagnosis, enrollment in early intervention, and those lost to follow-up at each stage in the process. EHDI programs that include in-patient and out-patient screening must be able to report specific results for both. The system must be able to accurately ascertain the outcome for every occurrent birth. The applicant should include a data flow chart describing how the disposition of every occurrent birth will be reported.

• Establish or improve methods (*e.g.*, linkage/integration with vital records and newborn dried bloodspot screening) to identify, match, collect, and report standardized unduplicated individual identifiable data (not estimated or only aggregate) on screening results including child date of birth, infant gender, maternal race, maternal ethnicity, and maternal education level, date of screen, results (*e.g.* pass/refer), screening equipment type, and number of families that refuse screening;

• Develop or improve reporting systems that will ensure that accurate tracking and surveillance of unduplicated individual identifiable data (not estimated or only aggregate) are collected, including data such as diagnosis (degree of hearing loss), intervention service (start date and type of service), date of hearing aid fit, and date of cochlear implant. This will necessitate information be obtained from multiple sources, *e.g.* birthing hospitals, diagnostic centers, audiologists, physicians (Medical Home), and intervention programs (Part C Early Intervention). Secure authenticated role-based Web access is encouraged;

• Develop or improve reporting systems that will ensure that unduplicated individual identifiable tracking and surveillance data collected from multiple sources will be used to minimize infants lost to follow-up (*e.g.* linkage/integration with immunization registries and birth defect registries);

• Develop or improve mechanisms to identify and collect standardized data on unduplicated individual infants/children with late onset or progressive hearing loss within the State/territory;

• Outline an analytic plan to use State/territorial level unduplicated individual identifiable (not estimated) EHDI data in order to obtain outcome data such as: Number/percent of infants screened (occurrent births), referred, evaluated, and enrolled in intervention programs; unexpected clusters of infants with hearing loss in particular regions at particular times; unexpected differences in EHDI screening performance between key variables such as participating birthing hospitals, racial ethnic sub-populations, gender and geographic location (urban vs. rural); false positive rates; loss to follow-up rates; developmental indicators such as language scores (quotients), socio-emotional levels, achievement scores, and or intelligence quotients;

• Design or enhance the program so that it can be integrated with other screening and tracking programs that identify unduplicated individual children with special health care needs such as newborn dried blood spot screening, birth defects registries, fetal alcohol syndrome surveillance, and part C of the Individuals with Disabilities Education Act (IDEA) [*http://www.nectac.org*];

• Collaborate with other State/territorial programs such as Maternal and Child Health (MCH) [*http://www.mchb.hrsa.gov*], part C of IDEA, private service programs, and advocacy groups to build a coordinated EHDI infrastructure;

• Develop a quality assurance/improvement plan to monitor the accuracy and quality of reportable data (*e.g.* independent chart review);

• Develop a carefully designed and well-planned evaluation plan to monitor progress on activities and to assess the timeliness, completeness, and success of the project (applicants are encouraged to review the Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports ''Updated Guidelines for Evaluating Public Health Surveillance Systems'' July 27, 2001/50(RR13);1–35 available at *http://www.cdc.gov/mmwr/PDF/RR/RR5013.pdf* and ''Framework for Program Evaluation in Public Health'' September 17, 1999/48(RR11);1–40 available at *http://www.cdc.gov/mmwr/PDF/RR/RR4811.pdf*). The plan should be based on a clear rationale relating the activities within the cooperative agreement, project goals, and evaluation measures. Wherever possible, the measurement of progress toward goals should focus on health outcome indicators, rather than on intermediate measures such as process or outputs;

• Prepare and publish manuscript(s) which describe(s) and document the tracking system, definitions, methodology, collaborative relationships, data collection, findings, and recommendations across sites. Peer-to-peer interaction and collaboration with participating EHDI programs, public health informatics, and related communities of practice is encouraged;

• Collaborate and share information on effective mechanisms for obtaining screening data with other State/territorial/tribal recipients, the CDC, and other Federal and national agencies. The decision on how to share information will be a collaboration among the States and other parties.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC will provide technical assistance as requested by the States/territories for this program as follows:

• Assist in designing, developing, and evaluating methodologies and

approaches used in State/territorial-based data collection and analysis of data across sites.

• Facilitate collaborative efforts to compile and disseminate program results through presentations and publications.

• Assist and provide technical assistance to States/territories on surveillance of systems including hospitals, audiologists, early intervention programs.

• Assist in analyzing surveillance data related to EHDI.

• Assist in designing, developing, and evaluating plans to improve the access of children with hearing loss to health services and intervention programs.

II. Award Information

Type of Award: Cooperative Agreement. CDC involvement in this program is listed in the Activities section above.

Fiscal Year Funds: 2005.

Approximate Total Funding: $4,800,000 (This amount is an estimate, and is subject to availability of funds.)

Approximate Number of Awards: 32.

Approximate Average Award: $150,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: $200,000 (This ceiling is for the first 12-month budget period.)

Anticipated Award Date: July 1, 2005.

Budget Period Length: 12 months.

Project Period Length: Three years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by governments and their agencies, such as:

• Federally recognized Indian tribal governments

• Indian tribes

• Indian tribal organizations

• State and local governments or their Bona Fide Agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)

A Bona Fide Agent is an agency/organization identified by the State as eligible to submit an application under the State eligibility in lieu of a State application. If you are applying as a bona fide agent of a State or local government, you must provide a letter from the State or local government as documentation of your status. Place this documentation behind the first page of your application form.

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

In order to receive new funding, current CDC–EHDI awardees under PA 00076, 01048, 00355 that successfully compete under this Program Announcement will have their existing budget/project periods end on June 30, 2005, and need to submit a Financial Status Report (FSR) within 90 days of this new end date. This FSR will be used to determine the amount of unobligated funds which can be requested to be carried over into the new budget period.

Special Requirements: If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process. You will be notified that your application did not meet submission requirements.

• Late applications will be considered non-responsive. See section ''IV.3. Submission Dates and Times'' for more information on deadlines.

To be eligible, applicants must document that they:

• Do not have an established State/territory centralized EHDI surveillance and tracking program; or

• Are in the beginning stages of establishing a centralized EHDI tracking and surveillance program; or

• Already have a program but would like to refine their existing surveillance and tracking program to integrate it with other newborn screening, tracking, and surveillance programs; and

• Have previously been awarded a CDC Cooperative Agreement for EHDI Tracking, Surveillance, and Integration (Program Announcements 00076, 01048, or 03055).

The applicant must include this documentation in the cover letter of the application. If it is not included, then the application will be determined as non-responsive and returned without review.

• Additionally, States or territories that have been awarded a previous CDC Cooperative Agreement for EHDI Tracking, Surveillance, and Integration (Program Announcements 00076, 01048, or 03055) need to document progress in developing an EHDI tracking and surveillance system, including reporting data from the most recent birth year. Data reports should include a flow chart with specific data accurately describing the disposition of every occurrent birth for each step throughout screening, evaluation, and intervention. The applicant should include this documentation in the narrative portion ''Understanding of the Problem and Current Status'' of the application.

Note: Title 2 of the United States Code Section 1611 states that an organization described in Section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address to Request Application Package

To apply for this funding opportunity use application form CDC 1246. Application forms and instructions are available on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/forminfo.htm*.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770–488–2700. Application forms can be mailed to you.

IV.2. Content and Form of Submission

Letter of Intent (LOI): Your LOI must be written in the following format:

• Maximum number of pages: Two

• Font size: 12-point unreduced

• Single spaced

• Paper size: 8.5 by 11 inches

• Page margin size: One inch

• Printed only on one side of page

• Written in plain language, avoid jargon

Your LOI must contain the following information:

• Program announcement number

• Program title

• Proposed project director

• The name of the organization

• Primary contact person's name

• Mailing address

• Telephone number and, if available, fax number and e-mail address

Application: Applications should include the following items, in the following order:

(1) Cover Letter: A one page cover letter stating that the applicant is applying and how the applicant fulfills eligibility requirements. Additionally, if the applicant is not the State health agency, the applicant must provide a letter from the appropriate State health agency designating the applicant as a bona fide agent. This information should be placed directly behind the cover letter of the application.

(2) Table of Contents: A table of contents that provides page numbers for the following sections should follow the abstract. All pages must be numbered.

(3) Narrative: You must submit a project narrative with your application forms. The narrative must be submitted in the following format:

- Maximum number of pages: 25 pages. If your narrative exceeds the page limit, only the first pages which are within the page limit will be reviewed.
- Font size: 12 point unreduced
- Double spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Held together only by rubber bands or metal clips; not bound in any other way.

Your narrative should provide a detailed description of first-year activities and briefly describe future year objectives and activities. It must include the following items in the order listed:

- Understanding of the Problem and Current Status
- Description of Proposed Program and Methodology
- Goals and Objectives
- Collaborative Efforts
- Evaluation Plan
- Staffing and Management System (One-page CV or resume for all key personnel must be included in an attachment). Plan must also provide details of the role of all key personnel.
- Organizational Structure and Facilities (Must include an organizational chart as an attachment)

(4) Budget and Budget Justification: The budget and budget justification will not be counted toward the narrative page limit. The budget should be reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant must include a detailed first-year budget which indicates the anticipated costs for personnel, fringe benefits, travel, supplies, contractual, consultants, equipment, indirect, and other items with future annual projections. Budgets should include travel funds for two project staff per each grant year to participate in mandatory CDC sponsored regional or annual meetings. The applicant should provide a budget justification for each budget item. Proposed sub-contracts should identify the name of the contractor, if known; describe the services to be performed; provide an itemized budget and justification for the estimated costs of the contract; specify the period of performance; and describe the method of selection.

(5) Additional information may be included in the application appendices. The appendices will not be counted toward the narrative page limit. This additional information includes:

- An organizational chart
- Data flow chart
- Time line Gant chart
- One-page CV or resume for all key personnel
- Letters of agreement and cooperation from collaborating programs

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711.

For more information, see the CDC Web site at: *http://www.cdc.gov/od/pgo/funding/pubcommt.htm.*

If your application form does not have a DUNS number field, please write your DUNS number at the top of the first page of your application, and/or include your DUNS number in your application cover letter.

Additional requirements that may require you to submit additional documentation with your application are listed in section ''VI.2. Administrative and National Policy Requirements.''

IV.3. Submission Dates and Times

LOI Deadline Date: February 3, 2005.

CDC requests that you send a LOI if you intend to apply for this program. Although the LOI is not required, not binding, and does not enter into the review of your subsequent application, the LOI will be used to gauge the level of interest in this program, and to allow CDC to plan the application review.

Application Deadline Date: March 7, 2005.

Explanation of Deadlines: Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you submit your application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on LOI and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your submission does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: 770–488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for State and local governmental review of proposed Federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: *http://www.whitehouse.gov/omb/grants/spoc.html*

IV.5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds may not be used for research.
- Reimbursement of pre-award costs is not allowed.
- Award recipients agree to use cooperative agreement funds for travel by project staff selected by CDC to participate in CDC-sponsored

workshops, or other called meetings such as regional or annual meetings.

• Funds may not be used to supplant other available applicant or collaborating agency funds or to supplant State/territory funds available for screening, diagnosis, intervention or tracking for hearing loss or other disorders detected by newborn screening.

• Funds may not be used for construction, for lease or purchase of facilities or space, purchase of screening and diagnostic equipment, or for patient care.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Guidance for completing your budget can be found on the CDC Web site, at the following Internet address: *http://www.cdc.gov/od/pgo/funding/budgetguide.htm.*

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to: John Eichwald, EHDI Team Lead, National Center for Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–88, Atlanta, GA 30333; Telephone: 404–498–3961; E-mail Address: *jeichwald@cdc.gov.*

Application Submission Address: Submit the original and two hard copies of your application by mail or express delivery service to: Technical Information Management–05028, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the ''Purpose'' section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

Your application will be evaluated against the following criteria:

1. Description of Program and Methodology (30 percent).

a. Extent to which applicant describes an effective and realistic plan to address the challenges, barriers, and problems described in section 4b ''Understanding the Problem and Current Status'' particularly those related to data requests that the EHDI program can not presently provide (*e.g.* maternal race, maternal ethnicity, maternal education level, results of in-patient and out-patient screening, audiologic results, referrals to early intervention, etc.);

b. Extent to which applicant describes the methods they will use establishing or improving methods to identify, match, collect, and report standardized unduplicated individual identifiable data for every occurrent birth;

c. Extent to which applicant describes the methods they will use developing or improving reporting systems that ensure that accurate tracking and surveillance of unduplicated individual identifiable data—secure authenticated role-based Web access is encouraged;

d. Extent to which applicant describes the methods they will use developing or improving reporting systems from multiple sources;

e. Extent to which applicant describes the methods they will use developing or improving mechanisms to identify late onset or progressive hearing loss;

f. Extent to which applicant describes the methods they will use designing an analytic plan;

g. Extent to which applicant describes the methods they will use preparing manuscripts.

2. Goals and Objectives (20 percent).

a. Extent to which applicant clearly describes the short- and long-term goals and measurable objectives of the project;

b. Extent to which applicant's goals and objectives are realistic and are consistent with the stated goals and purpose of this announcement;

c. Extent to which applicant provides a time line which includes activities to be accomplished and personnel responsible to complete the project. The inclusion of a schedule plotting the tasks, people responsible for these tasks, and a timeline (such as a Gant chart) is encouraged and can be included as an attachment;

3. Collaborative Efforts (20 percent).

a. Extent to which applicant describes and documents their methods for collaboration with multiple data sources (include written assurances) such as hospitals, diagnostic centers, and intervention service providers;

b. Extent to which collaborative relationships are documented which will facilitate linkage with other screening, tracking, and surveillance programs. Letters of agreement and cooperation from collaborating programs should be included (such as vital records, newborn dried bloodspot screening, immunization registries, birth defect registries, and notifiable disease systems);

c. Extent to which collaborative efforts with other relevant programs are documented (such as MCH, Early Intervention Part C, etc.);

d. Extent to which applicant describes their plans to work collaboratively with other state/territorial/tribal recipients, the CDC, and other federal and national agencies on effective mechanisms for obtaining data on screening.

4. Understanding the Problem and Current Status (10 percent).

a. Extent to which the applicant has a clear, concise understanding of the requirements and purpose of the cooperative agreement;

b. Extent to which the applicant understands the challenges, barriers, and problems associated with developing and improving an EHDI tracking and surveillance program including those with data collection;

c. Extent to which the applicant describes the need for funds to develop/enhance an EHDI tracking and surveillance program in their State or territory;

d. Extent to which the applicant describes the target population and the current status of their existing EHDI program, *i.e.*, accounting for all occurrent infants born, including number of infants screened, number of infants passing the screen, number of infants receiving audiological diagnosis, number of infants identified with hearing loss and number of infants receiving early intervention services;

e. Extent to which the applicant's data flow chart describes how the disposition of every occurrent birth will be reported.

f. Extent to which applicant describes (1) their current EHDI tracking and surveillance system (if any exists); (2) other relevant tracking, surveillance systems, or registries in the State/Territory; and (3) integration and linkages with other relevant systems;

5. Evaluation Plan (10 percent).

a. Extent to which applicant describes a plan for gathering necessary information for improving and accounting for program effectiveness;

b. Extent to which applicant describes an evaluation plan that will monitor progress toward their goals, and assess timeliness, completeness, and success of the objectives and activities of the project;

c. Extent to which applicant describes a plan that monitors the quality of the data being collected to include the

development of a data quality improvement plan.

6. Staffing and Management System (5 percent).

a. Extent to which key personnel have skills and experience to develop, implement or refine an EHDI tracking and surveillance system;

b. Extent of the managerial ability to coordinate the tracking, surveillance, and integration components of the project;

c. Extent to which expertise in abstracting screening, identification, and intervention records are demonstrated;

d. Extent to which expertise in epidemiologic methods, public health surveillance, data management and computer programming is demonstrated; and

e. Extent to which there is sufficient dedicated staff time to develop, implement or refine an EHDI tracking and surveillance system and to integrate the EHDI system with other newborn screening systems (include percentage of time each staff member will contribute to the project).

7. Organizational Structure and Facilities (5 percent)

Extent to which the organizational structure and the facilities/space/equipment are adequate in carrying out the activities of the program.

8. Budget (not scored).

The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds. The applicant shall describe and indicate the availability of facilities and equipment necessary to carry out this project.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO) staff, and for responsiveness by the National Center on Birth Defects and Developmental Disabilities (NCBDDD). Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

An objective review panel will evaluate complete and responsive applications according to the criteria listed in the ''V.1. Criteria'' section above. The objective review panel will consist of CDC employees who will be randomly assigned applications to review and score. Applications will be funded in order by score and rank determined by the review panel. CDC will provide justification for any decision to fund out of rank order.

V.3. Anticipated Announcement and Award Dates

[May 2005 for a] July 1, 2005, project start date.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.*

The following additional requirements apply to this project:

- AR–7 Executive Order 12372.
- AR–9 Paperwork Reduction Act Requirements.
- AR–10 Smoke-Free Workplace Requirements.
- AR–11 Healthy People 2010.
- AR–12 Lobbying Restrictions.
- AR–24 Health Insurance Portability and Accountability Act Requirements.
- AR–25 Release and Sharing of Data.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.*

VI.3. Reporting Requirements

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, due no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management or Contract Specialist listed in the ''Agency Contacts'' section of this announcement.

VII. Agency Contacts

We encourage inquiries concerning this announcement. For general questions, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: 770–488–2700.

For program technical assistance, contact: John Eichwald, EHDI Team Lead, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop E–88, Atlanta, GA 30333; Telephone: 404–498–3961; E-mail Address: *jeichwald@cdc.gov.*

For financial, grants management, or budget assistance, contact: Mildred Garner, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341; Telephone: 770–488–2745; E-mail: *MGarner@cdc.gov.*

VIII. Other Information

This and other CDC funding opportunity announcements can be found on the CDC Web site, Internet address: *http://www.cdc.gov.* Click on ''Funding'' then ''Grants and Cooperative Agreements.''

Dated: December 28, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0534]

Agency Information Collection Activities; Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.