Dated: February 3, 2010.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–2705 Filed 2–5–10; 8:45 am]

BILLING CODE 6730–01–P

FEDERAL MARITIME COMMISSION

Sunshine Act Meetings

TIME AND DATE: February 10, 2010—10 a.m.

PLACE: 800 North Capitol Street, NW., First Floor Hearing Room, Washington, DC.

STATUS: The meeting will be in Open Session.

MATTERS TO BE CONSIDERED:

Open Session

1. Docket No. 06–01: Worldwide Relocations, Inc.; *et al.,*—Possible Violations of Sections 8, 10, and 19 of the Shipping Act of 1984 and the Commission's Regulations at 46 CFR 515.3, 515.21, and 520.3—Request for Extension of Time.

2. Docket No. 08–04: *Tienshan, Inc.* v. *Tianjin Hua Feng Transport Agency Co., Ltd*—Request for Extension of Time.

3. FY 2010 Budget Status Update.

4. Petition P1–08—Petition of the National Customs Brokers and Forwarders Association of America, Inc. for Exemption from Mandatory Rate Tariff Publication.

CONTACT PERSON FOR MORE INFORMATION: Karen V. Gregory, Secretary, (202) 523–5725.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–2616 Filed 2–4–10; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–0747]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call Maryam I. Daneshvar, the CDC Reports Clearance Officer, at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Longitudinal follow-up of Youth with Attention-Deficit/Hyperactivity Disorder identified in Community Settings: Examining Health Status, Correlates, and Effects associated with treatment for ADHD (OMB #0920–0747, exp. 7/31/2010)—Revision—National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project will collect data from proxy respondents and youths with and without Attention-Deficit/Hyperactivity Disorder (ADHD). This program addresses the Healthy People 2010 focus area of Mental Health and Mental Disorders, and describes the prevalence, incidence, long-term outcomes, treatment(s), select co-morbid conditions, secondary conditions, and health risk behavior of youth with ADHD relative to youth without ADHD.

The National Center on Birth Defects and Developmental Disabilities at CDC promotes the health of children with developmental disorders. As part of these efforts, two contracts were awarded in FY 2007–2010 to follow up a sample of children originally enrolled in community-based epidemiological research on ADHD among elementary-aged youth, known as the Project to Learn about ADHD in Youth (PLAY Study Collaborative), which informed community-based prevalence, rates of comorbidity, and rates of health risk behaviors among elementary-age youth with and without ADHD as determined by a rigorous case definition developed by the principal investigators and in collaboration with CDC scientists.

The purpose of the longitudinal follow-up program is to study the long-term outcomes and health status for children with ADHD identified and treated in community settings through a systematic follow-up of the subjects who participated in the PLAY Study Collaborative. There is a considerable interest in the long-term outcomes of youth with ADHD as well as the effects of treatment, lack of treatment, and quality of care in average U.S. communities, emphasizing the public health importance of longitudinal research in this area.

Given the lack of detailed information about longitudinal development in children with and without ADHD, there is need to continue assessing the children into older adolescence. This program extends data collection for two additional waves.

Minor changes to the assessment instruments are planned in order to include age appropriate assessment of treatment and health risk behaviors in older adolescents, such as understanding motor vehicle operation and dating behavior.

There are no costs to the respondents other than their time. The total annual burden hours are 765.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
Parent	ADHD Communication and Knowledge	190	1	10/60
Parent	ADHD Treatment, Cost, and Client Satisfaction Questionnaire	190	1	10/60
Parent	ADHD Treatment Questionnaire	190	3	7/60
Parent	Brief Impairment Scale	190	1	4/60
Parent	Critical School Events (Middle School)	37	2	4/60
Parent	Critical School Events (High School)	153	2	4/60
Parent	Demographic Survey	190	1	5/60
Parent	Health Risk Behavior Survey (Middle School) 11–13 years	37	1	18/60
Parent	Health Risk Behavior Survey High School, 14+ years	153	1	22/60
Parent	Parent-Child Relationship Inventory	190	1	15/60
Parent	Parents' Mental Health Questionnaire	178	1	5/60
Parent	Quarterly update form	190	3	1/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Responses per respondent	Avg. burden per response (in hours)
Parent	Social Isolation/Support	178	1	2/60
Parent	Strengths and Difficulties Questionnaire (SDQ)	190	2	3/60
Parent	Vanderbilt Parent Rating Scale	190	2	10/60
Child	Brief Sensation Seeking Scale	190	1	1/60
Child	Conflict in Adolescent Dating Relationships	153	1	10/60
Child	Health Risk Behavior Survey (Middle School) 11–13 years	37	1	15/60
Child	Health Risk Behavior Survey (High School) 14+ years	153	1	25/60
Child	MARSH—Self Description Questionnaire v I, 7–12 years	15	1	5/60
Child	MARSH—Self Description Questionnaire v II, 13–15 years	90	1	7/60
Child	MARSH—Self Description Questionnaire v III 16+ years	85	1	9/60
Child	Social Inventory (High School) 14+ years	153	1	10/60
Child	Olweus Bullying Questionnaire (High School) 14+ years	153	1	7/60
Child	Pediatric Quality of Life Child (8–12)	15	1	5/60
Child	Pediatric Quality of Life Teen (13+)	175	1	5/60
Child	Youth Demographic Survey, 16+ years	85	1	5/60
Teacher	Teacher Survey	949	1	10/60

Dated: February 1, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–2600 Filed 2–5–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0489]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

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.

DATES: Fax written comments on the collection of information by March 10, 2010.

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: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0598. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

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.

Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications—21 CFR Section 493 (OMB Control Number 0910–0598)—Extension

Congress passed the Clinical Laboratory Improvements Amendment (CLIA) (Public Law 100–578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are "simple" and that have an "insignificant risk of an erroneous result" may obtain a certificate of waiver (42 U.S.C. 263a(c)(2)). The Secretary has delegated to FDA the authority to determine whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" under CLIA (69 FR 22849, April 27, 2004). This guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it "simple"; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results. Only new information collections not already approved are included in the estimate in the following table. Quick reference instructions are a short version of the instructions that are written in simple language and that can be posted.

The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting. Based on previous years experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and