

Non-Vessel Operating Common Carrier and Ocean Freight Forwarder Transportation Intermediary Applicants

Lambert Maritime Express, Inc., 3352 Castle Drive, Kenner, LA 70065.

Officers: Dina Patricia Derose, Secretary (Qualifying Individual), Manuel H. Lambert, President.

Anderson Cargo Services, Inc. dba Anderson Worldwide Logistics and Forwarding, Inc., 1045 Gemini Road, Fagan, MN 55121. *Officers:* Brian Wesely Anderson, CEO, Joel Ripley, Director of Logistics (Qualifying Individuals), Kathy Bear Anderson, CFO.

Ansa McAl (US) Inc. dba Amus Logistics, 11403 NW 39th Street, Miami, FL 33178. *Officers:* Steven P. Rosensteel, V. P. for Logistics (Qualifying Individual), Conrad O'Brien, President.

Ocean Freight Forwarder—Ocean Transportation Intermediary Applicants:

Ohanneson Freight Forwarding Co., 50 Indian Hill Road, Nicasio, CA 94946. *Officer:* Elizabeth A. Ohanneson, Sole Proprietor.

Gonzalez Exporting Corp. dba Goexco, 7349 NW 54th Street, Miami, FL 33166. *Officers:* Yolanda M. Gonzalez, President (Qualifying Individual), Dario Gonzalez, Director.

Shiplane Transport, Inc., 2620 N. Oak Park, Chicago, IL 60707. *Officers:* Elizabeth Esparza, President (Qualifying Individual).

Dated: June 25, 2004.

Bryant L. VanBrakle,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (ARHQ) to request the Office of Management and Budget (OMB) to allow the proposed information collection project: 2004–2006 Medical Expenditure Panel Survey—Insurance Component (MEPS–

IC). In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by August 30, 2004.

ADDRESSES: Written comments should be submitted to: Cynthia McMichael, Reports Clearance Officer, AHRQ, 540 Gaither Road, Room 5202, Rockville, MD 20850.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Cynthia McMichael, AHRQ Reports Clearance Officer, (301) 427-1651.

SUPPLEMENTARY INFORMATION:

Proposed Project

2004–2006 Medical Expenditure Panel Survey—Insurance Component (MEPS–IC).

The MEPS–IC, an annual survey of the characteristics of employer-sponsored health insurance, was first conducted by AHRQ in 1997 for the calendar year 1996. The survey has since been conducted annually for calendar years 1997 through 2003. AHRQ proposes to continue this annual survey of establishments for calendar years 2004 through 2006. The survey data for calendar year 2004 will be collected in 2005. Likewise, calendar year 2005 will be collected in 2006 and calendar year 2006 data in 2007. The survey will collect information from both public and private employers.

This survey will be conducted for AHRQ by the Bureau of the Census using a sample comprised of:

1. An annual sample of employers selected from Census Bureau lists of private sector employers and governments (known as the List Sample), and
2. An every fourth year sample of employers identified by respondents to the MEPS–Household Component (MEPS–HC) for the same calendar year (known as the Household Sample). The MEPS–HC is an annual household survey designed to collect information concerning health care expenditures and related data for individuals. This sample is next scheduled to be collected for the 2006 survey year.

Data to be collected from each employer will include a description of the business (e.g., size, industry) and descriptions of health insurance plans available, plan enrollments, total plan costs and costs to employees.

Data Confidentiality Provisions

MEPS–IC List Sample data confidentiality is protected under the U.S. Census Bureau confidentiality statute, Section 9 of Title 13, United States Code. MEPS–IC Household Sample data confidentiality is protected under sections 308(d) and 924(c) of the Public Health Service Act (42 U.S.C. 242m and 42 U.S.C. 299c–3(c)).

Section 308(d), the confidentiality statute of the National Center for Health Statistics, is applicable because the MEPS–HC sample is derived from respondents of an earlier NCHS survey. Section 924(c), the confidentiality statute of AHRQ, applies to all data collected for research that is supported by AHRQ. All data products listed below must fully comply with the data confidentiality statute under which the raw data was collected as well as any additional confidentiality provisions that apply.

Data Products

Data will be produced in three forms: (1) Files derived from the Household Sample, which can be linked back to other information from household respondents in the MEPS–HC, will be available to researchers at the AHRQ Research Data Center; (2) files containing employer information from the List Sample will be available for use by researchers at the Census Bureau's Research Data Centers; and (3) a large compendium of tables of estimates, also based on List Sample data, will be produced and made available on the AHRQ website. These tables will contain descriptive, but non-identifiable statistics, such as, numbers of establishments offering health insurance, average premiums, average contributions, total enrollments, numbers of self insured establishments and other related statistics for a large number of population subsets defined by firm size, state, industry and establishment characteristics, such as, age, profit/nonprofit status and union/non-union.

The data are intended to be used for purposes such as:

- Generating national and State estimates of employer health insurance offerings;
- Producing estimates to support the Bureau of Economic Analysis and the Center for Medicare and Medicaid Services in their production of health care expenditure estimates for the National Health Accounts and the Gross Domestic Product;
- Producing national and State estimates of spending on employer-sponsored health insurance to study the

results of national and State health care policies;

- Supply data for modeling the demand for health insurance; and
- Providing data on health plan choices, costs, and benefits that can be linked back to households' use of health care resources in the MEPS-HC for studies of the consumer health insurance selection process.

These data provide the basis for researchers to address important questions for employers and policymakers alike.

Method of Collection

The data will be collected using a combination of modes. The Census Bureau's first contact with employers will be made by telephone. This contact will provide information on the availability of health insurance from that employer and essential persons to contact. Based upon this information, Census will mail a questionnaire to the employer.

In order to assure high response rates, Census will follow-up with a second

mailing after an interval of approximately 30 working days, followed by a telephone call to collect data from those who have not responded by mail.

As part of this process, for larger respondents with high burdens, such as State employers and very large firms, we will, if needed, perform personal visits and do customized collection, such as, acceptance of data in computerized formats and use of special forms.

Estimated Annual Respondent Burden

Survey years	Annual number of respondents	Estimated time per respondent in hours	Estimated total annual burden hours	Estimated annual cost to the government
2004	34,507	.6	19,708	\$8,800,000
2005	34,507	.6	19,708	9,138,000
2006	39,791	.6	23,550	10,660,000

Request for Comments

In accordance with the above cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of functions of the AHRQ, including whether the information will have practical utility; (b) the accuracy of the AHRQ's estimate of the burden (including hours and costs) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: June 23, 2004.

Carolyn M. Clancy,

Director.

[FR Doc. 04-14734 Filed 6-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Correction—Technical Review Meeting Date

The original notice was published in the **Federal Register** on June 10, 2004 under Volume 69, Number 112, Pages 32558-32559 (<http://a257.g.akamaitech.net/7257/2422/06jun20041800/edocket.access.gpo.gov/2004/04-13102.htm>). With this Notice, the Agency for Healthcare Research and Quality (AHRQ) is informing the public that the correct meeting date for the "AHRQ State and Regional Demonstrations in Health Information Technology" is July 7 and 8, 2004.

Dated: June 23, 2004.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 04-14733 Filed 6-29-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004M-0203]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and FDA's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at <http://www.fda.gov>. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were