

**SUPPLEMENTARY INFORMATION:** You may call 202-452-3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, August 3, 2010.  
**Robert deV. Frierson,**  
*Deputy Secretary of the Board.*  
 [FR Doc. 2010-19471 Filed 8-3-10; 4:15 pm]  
**BILLING CODE 6210-01-S**

Intermediary licenses have been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. chapter 409) and the regulations of the Commission pertaining to the licensing of Ocean Transportation Intermediaries, 46 CFR part 515.

**FEDERAL MARITIME COMMISSION**

**Ocean Transportation Intermediary License Reissuance**

Notice is hereby given that the following Ocean Transportation

License No.	Name/address	Date reissued
015941N .....	Cargo Plus, Inc., 8333 Wessex Drive, Pennsauken, NJ 08109 .....	June 23, 2010.
18547N .....	Pallets in Motion, 426 W. Florence Avenue, Inglewood, CA 90301 .....	June 26, 2010.
020151NF .....	United Global Logistics, LLC, 1139 East Jersey Street, Suite 417, Elizabeth, NJ 07201. ....	May 27, 2010.

**Sandra L. Kusumoto,**  
*Director, Bureau of Certification and Licensing.*  
 [FR Doc. 2010-19146 Filed 8-4-10; 8:45 am]  
**BILLING CODE P**

Dated: July 30, 2010.  
**Sherry Glied,**  
*Assistant Secretary for Planning and Evaluation.*  
 [FR Doc. 2010-19211 Filed 8-2-10; 4:15 pm]  
**BILLING CODE 4151-05-P**

elect to operate a title IV-E program with an approved title IV-E plan. Tribes are to operate a program in the same manner as states and must provide for a case plan for each child and for a case review system.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Office of the Assistant Secretary for Planning and Evaluation; Technical Review Panel on the Medicare Trustees Reports**

**AGENCY:** Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation.

**ACTION:** Notice; correction.

**SUMMARY:** This document corrects the fax number and adds an e-mail address for Marian Robinson found in the **Federal Register** (FR) on July 30, 2010, entitled "Technical Review Panel on the Medicare Trustees Reports". The FR notice should have the corrected fax number of 202-260-2524 and should include the e-mail address for Marian Robinson ([marian.robinson@hhs.gov](mailto:marian.robinson@hhs.gov)).

**Applicability Date:** The corrections in this notice are applicable on and after August 2, 2010.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Case Plan Requirement, Title IV-E of the Social Security Act.  
*OMB No.:* 0980-0140.

*Description:* Under section 471(a)(16) of title IV-E of the Social Security Act (the Act), to be eligible for payments, states must have an approved title IV-E plan that provides for the development of a case plan for each child for whom the State receives foster care maintenance payments and that provides a case review system that meets the requirements in section 475(5) and 475(6) of the Act. The Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110-351) added a new section 479B to the Act providing authority at 479B(b) for an Indian Tribe, tribal organization or tribal consortia (hereafter "Tribe") to

The case review system assures that each child has a case plan designed to achieve placement in a safe setting that is the least restrictive (most family-like) setting available and in close proximity to the child's parental home, consistent with the best interest and special needs of the child. Through these requirements, States and Tribes also comply, in part, with title IV-B section 422(b) of the Act, which assures certain protections for children in foster care.

The case plan is a written document that provides a narrative description of the child-specific program of care. Federal regulations at 45 CFR 1356.21(g) and section 475(1) of the Act delineate the specific information that should be addressed in the case plan. The Administration for Children and Families (ACF) does not specify a recordkeeping format for the case plan nor does ACF require submission of the document to the Federal government. Case plan information is recorded in a format developed and maintained by the State or Tribal child welfare agency.

**Respondents:** State and Tribe title IV-B and title IV-E agencies

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Plan .....	603,453	1	4.79	2,890,539.87

Estimated Total Annual Burden Hours: 2,890,539.87

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-7285, E-mail: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

Dated: August 2, 2010.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2010-19268 Filed 8-4-10; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0348]

#### Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability for public comment of a two-volume set of documents entitled "Center for Devices and Radiological Health Preliminary Internal Evaluations," which is comprised of the preliminary reports of two internal committees: The 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. Volume I is entitled "510(k) Working

Group Preliminary Report and Recommendations." Volume II is entitled "Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations." The recommendations contained in these reports are preliminary. FDA has not made any decisions on specific changes to pursue. FDA is soliciting public input on the recommendations discussed in these reports, including the feasibility of implementation and potential alternatives. Once its assessment of public input and other necessary reviews are completed, FDA will announce which improvements it will implement, as well as projected timelines for implementation.

**DATES:** Submit either electronic or written comments on the preliminary report by October 4, 2010.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit electronic comments on the preliminary report to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Philip Desjardins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5447, Silver Spring, MD 20993-0002, 301-796-5678.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

##### A. 510(k) Working Group

The premarket notification (510(k)) process for the review of medical devices was established in 1976, under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (FDCA). With the exception of certain low-risk devices that are exempt from premarket submission requirements, a medical device that is first introduced into the market after May 28, 1976 (a postamendment device) may be legally marketed without an approved premarket approval application (PMA) if FDA concludes through review of a 510(k) submission that the device meets the comparative standard of "substantial equivalence" to a "predicate" device. Substantial equivalence may be determined by a comparison to a device that was legally marketed prior to May 28, 1976 (a preamendment device), to a device that has been reclassified from

class III (high-risk) to class II or class I (medium- to low-risk), or to a device that has previously been cleared through the 510(k) process.

Since its inception, the 510(k) process has undergone a number of statutory changes. In addition, FDA has modified its implementation of the process to adapt to changing circumstances and accommodate the evolving medical device landscape. The current 510(k) program reflects the current statutory framework and FDA's implementation of that framework through regulation, guidance, and administrative practice.

The 510(k) program, as it currently exists, is intended to support FDA's public health mission by meeting two important goals: making available to consumers devices that are safe and effective, and fostering innovation in the medical device industry. In recent years, concerns have been raised within and outside of FDA about whether the current 510(k) program optimally achieves these goals.

In September 2009, CDRH convened an internal 510(k) Working Group as part of a two-pronged, comprehensive assessment of the 510(k) process. The other component of this assessment is an ongoing independent study by the Institute of Medicine, which is expected to conclude in the summer of 2011. The 510(k) Working Group was charged to evaluate the 510(k) program and explore actions CDRH could take to strengthen the program and improve the consistency of its decision making, with a principal focus on actions the Center could take in the short term under its existing statutory authority.

#### B. Task Force on the Utilization of Science in Regulatory Decision Making

CDRH uses science to guide its regulatory decision making across the total product life cycle of medical devices and radiation-emitting products. At any stage of that life cycle, CDRH may encounter new, unfamiliar, or unexpected information that may influence its thinking, expectations, and actions. To fulfill its mission to protect and promote the public health, CDRH must strike a balance between the ability to adapt its approach as necessary as new science emerges, and the desire to provide predictable regulatory pathways that foster innovation.

In September 2009, CDRH convened an internal Task Force on the Utilization of Science in Regulatory Decision Making to review how CDRH uses science in its regulatory decision making, and to make recommendations on how the Center can quickly incorporate new science—including