

*Synopsis:* The amendment changes the name of NYKCool AB to Cool Carriers AB and makes related conforming changes.

*Agreement No.:* 012326.

*Title:* CSCL/HSD Slot Charter Agreement

*Parties:* China Shipping Container Lines Co., Ltd. and China Shipping Container Lines (Hong Kong) Co., Ltd. (acting as a single party); and Hamburg Sud.

*Filing Party:* Patricia M. O'Neill; Blank & Rome LLP; 600 New Hampshire Ave., NW., Washington, DC 20037.

*Synopsis:* The agreement authorizes Hamburg Sud to charter slots on services operated by CSCL in the trade between China and Korea, on the one hand, and the U.S. West Coast on the other hand.

*Agreement No.:* 012327.

*Title:* "K" Line/WHL/WHS/PIL Space Charter and Sailing Agreement

*Parties:* Kawasaki Kisen Kaisha, Ltd.; Wan Hai Lines (Singapore) PTE Ltd.; Wan Hai Lines Ltd.; Pacific International Lines (PTE) Ltd.

*Filing Party:* Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW, Suite 900; Washington, DC 20004.

*Synopsis:* The agreement authorizes the parties to operate a joint service in the trade between the U.S. West Coast on the one hand, and China (including Hong Kong) and Japan on the other hand.

By Order of the Federal Maritime Commission.

Dated: April 10, 2015.

**Rachel E. Dickon,**

*Assistant Secretary.*

[FR Doc. 2015-08644 Filed 4-14-15; 8:45 am]

**BILLING CODE 6731-AA-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank

indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 30, 2015.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480-0291:

1. *Christian David Heitzman, Minneapolis, Minnesota*, to retain 25 percent or more of the shares of First BancShares, Inc., of Cold Spring, Cold Spring, Minnesota, and thereby indirectly retain control of Granite Community Bank, Cold Spring, Minnesota.

Board of Governors of the Federal Reserve System, April 9, 2015.

**Michael J. Lewandowski,**

*Assistant Secretary of the Board.*

[FR Doc. 2015-08623 Filed 4-14-15; 8:45 am]

**BILLING CODE 6210-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Community Living

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Annual Reporting Requirements for the Older American Act Title VI Grant Program

**AGENCY:** Administration for Community Living, HHS.

**ACTION:** Notice.

**SUMMARY:** The Administration on Aging Office (AoA), within the Administration for Community Living (ACL) is announcing an opportunity for public comment on the proposed extension of an existing collection of information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to Performance Reports for Title VI grants.

**DATES:** Submit written or electronic comments on the collection of information by June 15, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to: *Cynthia.Lacounte@acl.hhs.gov*. Submit written comments on the collection of information to Cynthia Lacounte, ACL/Administration

on Aging, Washington, DC 20201 or by fax at (202-357-3560).

**FOR FURTHER INFORMATION CONTACT:**

Margaret Graves at (202) 357-3502 or *Margaret.Graves@acl.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL/AoA is publishing notice of the proposed collection of information set forth in this document. With respect to the following collection of information, ACL/AoA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL/AoA's functions, including whether the information will have practical utility; (2) the accuracy of ACL/AoA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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 respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology. ACL/AoA estimates the burden of this collection of information as follows: Annual submission of the Program Performance Reports are due 90 days after the end of the budget period and final project period.

*Respondents:* Federally Recognized Tribes, Tribal and Native Hawaiian Organizations receiving grants under Title VI, Part A, Grants for Native Americans; Title VI, Part B, Native Hawaiian Program and Title VI, Part C, Native American Caregiver Support Program.

*Estimated Number of Responses:* 266.

*Total Estimated Burden Hours:* 731.5.

Dated: April 9, 2015.

**Kathy Greenlee,**

*Administrator and Assistant Secretary for Aging.*

[FR Doc. 2015-08654 Filed 4-14-15; 8:45 am]

**BILLING CODE 4154-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-E-0688]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; AUBAGIO—Patent No. 5,679,709

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for AUBAGIO and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus Rm. 3180, Silver Spring, MD 20993, 301-796-7900.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis

for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product AUBAGIO (teriflunomide). AUBAGIO is indicated for treatment of patients with relapsing forms of multiple sclerosis. Subsequent to this approval, the USPTO received a patent term restoration application for AUBAGIO (U.S. Patent No. 5,679,709) from sanofi-aventis Deutschland GMBH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 31, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of AUBAGIO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for AUBAGIO is 2,940 days. Of this time, 2,542 days occurred during the testing phase of the regulatory review period, while 398 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* August 27, 2004. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on August 27, 2004.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* August 12, 2011. FDA has verified the applicant's

claim that the new drug application (NDA) for AUBAGIO (NDA 202992) was submitted on August 12, 2011.

3. *The date the application was approved:* September 12, 2012. FDA has verified the applicant's claim that NDA 202992 was approved on September 12, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 15, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 13, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA-2013-S-0610.

Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 8, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-08615 Filed 4-14-15; 8:45 am]

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