

exclusive dealing contract with Peavey had fostered L&C's entry. It is likely that an upstart firm such as L&C could be successful only if it could enter exclusive deals.

Finally, the settlement prohibited L&C from proposing or supporting a rate structure that did not have the essential features of the current rate structure. This provision substantially reduced competition in the rate-setting process. Rates are set by the Board after soliciting proposals from shippers and pilot groups.

The settlement permitted L&C to continue to compete, although at a diminished level. The penalties imposed by COLRIP on pilots leaving to compete with COLRIP were devastating to competition. Because L&C could not recruit new pilots, L&C was forced to exit the market when its founding members retired.

The complaint charges that COLRIP's penalties on pilots leaving to compete and its settlement with L&C violate Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. COLRIP's penalties on pilots leaving to compete with COLRIP protected COLRIP from additional competition. Not one pilot left to compete with COLRIP, either by joining L&C or by forming another pilotable group, after COLRIP adopted these penalties. Indeed, no pilot has left COLRIP since L&C's founders retired and COLRIP regained its monopoly. L&C's pilotage business was very profitable and, absent COLRIP's draconian penalties, should have attracted competition. In addition, COLRIP's settlement with L&C all but eliminated the ability of L&C to compete with COLRIP before L&C exited the market. The settlement substantially limited L&C's ability to offer pilotage to customers other than Peavey Grain Company and reduced L&C's ability to influence rates before the Oregon Board of Maritime Pilots. The settlement provisions and the penalties on departing pilots were not justified on efficiency grounds.

The proposed consent order would prohibit COLRIP from penalizing marine pilots who leave to compete with COLRIP, except where a pilot either has been a member of COLRIP for less than five years or fails to give COLRIP ninety days' notice of his intention to leave. COLRIP is also required to notify its members and the local shippers' association of this prohibition.

COLRIP's ability to penalize pilots who leave before serving five years appears unlikely to prevent competition in pilotage, since it affects only 25% of

COLRIP's members. Approximately 75% of COLRIP's marine pilots would immediately be free to leave COLRIP without a penalty. Moreover, it appears reasonable for COLRIP to demand that pilots remain for some period after COLRIP has trained them. Similarly, the notice requirement appears too brief to reduce significantly a pilot's incentive to leave and would afford COLRIP the opportunity to attend to internal issues raised by a departure, such as pilot scheduling changes and any contractual pay-outs required by a departure.

Should competition emerge, the proposed consent order also would protect that competition by prohibiting COLRIP from entering into agreements similar to the ones with L&C. That is, COLRIP cannot agree with a competitor to allocate customers, limit a competitor's size, or restrict the competitor's ability to enter exclusive agreements with customers or to submit rate proposals or otherwise communicate with the Oregon Board of Maritime Pilots. Finally, COLRIP cannot prevent a COLRIP marine pilot from recommending or otherwise supporting an applicant for a pilot's license or for training to obtain one. This restriction on COLRIP should encourage more applicants and expand the number of available pilots.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments from interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

The purpose of this analysis is to assist public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement containing the proposed consent order or to modify in any way its terms.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 98-33706 Filed 12-18-98; 8:45 am]

BILLING CODE 6750-01-M

## GENERAL SERVICES ADMINISTRATION

### Federal Supply Service; Solicitation for a Third Party Logistics Provider To Perform Freight Shipment Management Services

**AGENCY:** Federal Supply Service, GSA.

**ACTION:** Notice of Extension to comment period.

**SUMMARY:** GSA published for comment in the **Federal Register** on August 7, 1998, a notice advising industry of a solicitation for Third Party Logistics Services for a freight shipment test pilot project (63 FR 42402). The solicitation was revised to address issues raised by industry as well as to incorporate ideas generated by GSA's research and discussions. GSA issued the revised draft solicitation on October 22, 1998, and announced it in the *Commerce Business Daily* but not in the **Federal Register**. At a November 16, 1998, industry briefing on the revised draft solicitation GSA officials requested industry comments by December 4, 1998. This notice advises that GSA is extending the comment period, announced in the November 16, 1998 industry briefing as set forth below in the **DATES** paragraph.

**DATES:** Please submit your comments by Friday, January 8, 1999.

**ADDRESSES:** Mail comments to Ms. Patricia G. Walker, Contracting Officer, Contract Management Division (4FQ-P), GSA, FSS, 401 W. Peachtree Street, NW, Suite 2600, Atlanta, GA 30365-2550, Attn: 3PL Solicitation.

**FOR FURTHER INFORMATION CONTACT:** Ms. Patricia G. Walker, Contracting Officer, in writing at Contract Management Division, (4FQ-P), GSA, FSS, 401 W. Peachtree Street, NW, Suite 2600, Atlanta, GA 30365-2550, Attn: 3PL Solicitation; by phone at 404-331-3059; or by e-mail at patriciag.walker@gsa.gov.

**SUPPLEMENTARY INFORMATION:** In the draft solicitation, GSA proposed to change a variety of procedures now used under its transportation program. Proposed new procedures to be performed by the contractor include:

- (a) Using commercial forms and/or electronic commerce for shipment processing and invoicing;
- (b) Pre-screening carriers for participation in GSA's freight program;
- (c) Selecting carriers based on the greatest value advantage to the Government;
- (d) Attaining cost efficiencies through use of multiple procurement strategies;
- (e) Managing freight shipments from receipt of shipment data through delivery;
- (f) Tracking/tracing shipments and providing access to tracking/tracing information via the Internet so GSA customers can monitor shipment status;
- (g) Managing loss and damage claims from receipt of loss/damage reports to filing, tracking, monitoring, and settling claims; and

(h) Paying carriers for provided transportation services through use of a Government charge card.

Dated: December 14, 1998.

Allan J. Zaic,

Assistant Commissioner, Office of Transportation and Property Management.

[FR Doc. 98-33687 Filed 12-18-98; 8:45 am]

BILLING CODE 6820-24-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0478]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Requip

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for Requip 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 Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-6620.

**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 Commissioner of Patents and Trademarks 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 recently approved for marketing the human drug product Requip (ropinirole). Requip is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Requip (U.S. Patent No. 4,452,808) from SmithKline Beecham Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated September 9, 1998, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Requip represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Requip is 3,356 days. Of this time, 2,729 days occurred during the testing phase of the regulatory review period, while 627 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective:* July 14, 1988. The applicant claims July 10, 1988, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 14, 1988, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act:* January 2, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Requip (NDA 20-658) was initially submitted on January 2, 1996.

3. *The date the application was approved:* September 19, 1997. FDA has verified the applicant's claim that NDA 20-658 was approved on September 19, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 21, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. 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.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98-33639 Filed 12-18-98; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98E-0788]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; Sucralose

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined