

values, and supports employee and public diversity and inclusion;

- Develop objectives within the Agency's operation and strategic planning process to meet the goals of EEO and this policy;
- Implement affirmative programs to carry out this policy within the Agency; and
- To the extent practicable, seek to encourage the Farm Credit System to continue its efforts to promote and increase diversity.

#### DIVERSITY AND INCLUSION

The FCA intends to be a model employer. That is, as far as possible, FCA will build and maintain a workforce that reflects the rich diversity of individual differences evident throughout this Nation. The Board views individual differences as complementary and believes these differences enrich our organization. When individual differences are respected, recognized, and valued, diversity becomes a powerful force that can contribute to achieving superior results. Therefore, we will create, maintain, and continuously improve on an organizational culture that fully recognizes, values, and supports employee diversity. The Board is committed to promoting and supporting an inclusive environment that provides to all employees, individually and collectively, the chance to work to their full potential in the pursuit of the Agency's mission. We will provide everyone the opportunity to develop to his or her fullest potential. When a barrier to someone achieving this goal exists, we will strive to remove this barrier.

#### AFFIRMATIVE EMPLOYMENT

The Board reaffirms its commitment to ensuring FCA conducts all of its employment practices in a nondiscriminatory manner. The Board expects full cooperation and support from everyone associated with recruitment, selection, development, and promotion to ensure such actions are free of discrimination. All employees will be evaluated on their EEO achievements as part of their overall job performance. Though staff commitment is important, the role of supervisors is paramount to success. Agency supervisors must be coaches and are responsible for helping all employees develop their talents and give their best efforts in contributing to the mission of the FCA.

#### WORKPLACE HARASSMENT

It is the policy of the FCA to provide a work environment free from unlawful

discrimination in any form, and to protect all employees from any form of harassment, either physical or verbal. The FCA will not tolerate harassment in the workplace for any reason. The FCA also will not tolerate retaliation against any employee for reporting harassment or for aiding in any inquiry about reporting harassment.

#### DISABLED VETERANS AFFIRMATIVE ACTION PROGRAM (DVAAP)

A disabled veteran is defined as someone who is entitled to compensation under the laws administered by the Veterans Administration or someone who was discharged or released from active duty because of a service-connected disability.

The FCA is committed to increasing the representation of disabled veterans within its organization. Our Nation owes a debt to those veterans who served their country, especially those who were disabled because of service. To honor these disabled veterans, the FCA shall place emphasis on making vacancies known to and providing opportunities for employing disabled veterans.

Dated this 18th day of August, 2015.

By Order of the Board.

**Dale L. Aultman,**

*Secretary, Farm Credit Administration Board.*

[FR Doc. 2015-21175 Filed 8-25-15; 8:45 am]

BILLING CODE 6705-01-P

#### FEDERAL MARITIME COMMISSION

##### Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 011383-046.

*Title:* Venezuelan Discussion Agreement.

*Parties:* Hamburg-Süd; King Ocean Services Limited, Inc.; Seaboard Marine Ltd.; and Seafreight Line.

*Filing Party:* Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

*Synopsis:* The amendment deletes MSC Mediterranean Shipping Company as a party to the Agreement.

*Agreement No.:* 011426-059.

*Title:* West Coast of South America Discussion Agreement.

*Parties:* CMA CGM S.A.; Hamburg-Süd; Hapag-Lloyd AG; King Ocean Services Limited, Inc.; MSC Mediterranean Shipping Company, SA; Seaboard Marine Ltd.; and Trinity Shipping Line.

*Filing Party:* Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

*Synopsis:* The amendment deletes Frontier Liner Services, Inc. as a party to the agreement.

By Order of the Federal Maritime Commission.

Dated: August 21, 2015.

**Rachel E. Dickon,**

*Assistant Secretary.*

[FR Doc. 2015-21134 Filed 8-25-15; 8:45 am]

BILLING CODE 6731-AA-P

#### FEDERAL TRADE COMMISSION

[File No. 151 0030]

##### Par Pharmaceutical, Inc. and Concordia Pharmaceuticals, Inc.; Analysis of Proposed Consent Orders to Aid Public Comment

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreements.

**SUMMARY:** The consent agreements in this matter settle alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the two consent orders—embodied in the consent agreements—that would settle these allegations.

**DATES:** Comments must be received on or before September 17, 2015.

**ADDRESSES:** Interested parties may file a comment at <https://ftcpublish.commentworks.com/ftc/concordiaparconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Concordia Pharmaceuticals, Inc., et al—Consent Agreements; File No. 151-0030" on your comment and file your comment online at <https://ftcpublish.commentworks.com/ftc/concordiaparconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Concordia

Pharmaceuticals, Inc., *et al.*—Consent Agreements; File No. 151–0030” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:**

Bradley S. Albert, Bureau of Competition, (202–326–3670), 600 Pennsylvania Avenue NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 § CFR 2.34, notice is hereby given that the above-captioned consent agreements containing consent orders to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, have been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreements, and the allegations in the complaint. An electronic copy of the full text of the each consent agreement package can be obtained from the FTC Home Page (for August 18, 2015), on the World Wide Web, at <http://www.ftc.gov/os/actions.shtm>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 17, 2015. Write “Concordia Pharmaceuticals, Inc., *et al.*—Consent Agreements; File No. 151–0030” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals’ home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone’s Social Security number, date of birth, driver’s license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible

for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any “[t]rade secret or any commercial or financial information which . . . is privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 § CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 § CFR 4.9(c).<sup>1</sup> Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublic.commentworks.com/ftc/concordiaparconsent> by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!/home>, you also may file a comment through that Web site.

If you file your comment on paper, write “Concordia Pharmaceuticals, Inc., *et al.*—Consent Agreements; File No. 151–0030” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the

<sup>1</sup> In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR § 4.9(c).

Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before September 17, 2015. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

**Analysis of Agreements Containing Consent Orders to Aid Public Comment**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, Agreements Containing Consent Orders with Par Pharmaceutical, Inc., Par Pharmaceutical Holdings, Inc., TPG Partners VI, L.P. (hereinafter “Par”), and with Concordia Pharmaceuticals Inc., and Concordia Healthcare Corp. (hereinafter “Concordia”). The proposed orders are designed to settle allegations that Par and Concordia violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by entering into an unlawful agreement not to compete relating to generic versions of Concordia’s prescription drug known as Kapvay.

The proposed orders have been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreements and the comments received and will decide whether it should withdraw from the agreement or make the proposed orders final.

The purpose of this analysis is to facilitate public comment on the proposed orders. This Analysis to Aid Public Comment is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent orders, or to modify their terms in any way. The proposed consent orders have been entered into for settlement purposes only and do not constitute admissions by Par or Concordia that either violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

**Background and the Challenged Conduct**

The complaint charges that Par and Concordia entered an unlawful agreement that Concordia would refrain from launching an “authorized generic” version of its brand-name drug Kapvay in exchange for a share of the supra-competitive profits Par would earn as the sole seller of generic Kapvay.

An authorized generic is a prescription drug that has been approved by the FDA as a brand-name drug product, but is marketed by the brand company (or its representative) as a generic drug product, without the trademark of the brand-name drug. An authorized generic can be sold under the approval the FDA granted under a new drug application (NDA) at any time.<sup>2</sup> Brand-name drug companies frequently introduce authorized generics upon entry of the first generic to stem large losses resulting from the rapid shift of sales from brand-name drugs to lower-priced generic products. Empirical evidence from the Federal Trade Commission's Authorized Generic Study shows that competition between the first generic entrant and an authorized generic typically drives down both retail and wholesale generic drug prices.<sup>3</sup>

Competition from an authorized generic has significant financial implications for the first generic entrant, for two reasons: (1) The authorized generic typically takes substantial sales from the first entrant; and (2) the competition from an authorized generic means that, on average, sales are made at lower prices. When the first generic entrant is the sole seller of the generic drug product, it enjoys approximately double the revenues that it would otherwise make in the first six months on the market if it faced competition from an authorized generic.<sup>4</sup>

#### *As alleged in the complaint:*

Concordia owns and markets various brand-name drug products. It acquired the rights to Kapvay in May 2013. Kapvay is a non-stimulant medication for the treatment of attention deficit hyperactivity disorder, approved for sale in the United States in September 2010.

Par develops and markets generic drugs. Par filed an application seeking FDA approval to sell a generic version of Kapvay in March 2011.

The timing of FDA approval for an independent generic drug is subject to certain patent and regulatory exclusivity protections. The federal law commonly known as the Hatch-Waxman Act requires a brand-name drug manufacturer to notify the FDA of patents that could reasonably be asserted against a party making or

selling its drug. The FDA publishes patent information in a document known as the "Orange Book." If a generic drug manufacturer seeks FDA approval to market a generic product prior to the expiration of a listed patent or patents relating to the brand-name drug upon which the generic is based, the applicant must: (1) Certify to the FDA that the patent in question is invalid or is not infringed by the generic product (known as a "paragraph IV certification"); and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, unless before that time the patent expires or is judicially determined to be invalid or not infringed.

In the case of Kapvay, the single patent listed in the FDA's Orange Book expired on October 13, 2013 (U.S. Patent No. 5,869,100 ("the '100 patent")). When Par filed its application for approval of its generic Kapvay product in 2011, it submitted a paragraph IV certification concerning this patent. The company that held the rights to Kapvay at the time did not assert any claim for patent infringement.

Approximately five weeks before the '100 patent was due to expire, however, Par and Concordia entered into a "License Agreement" relating to Kapvay. The agreement granted Par a license effective one week before expiration of the '100 patent. Under this agreement, Concordia agreed not to market an authorized generic version of Kapvay for five years. Par in turn agreed to pay Concordia at least 35 percent (and as much as 50 percent) of the net profits from the sale of Par's generic Kapvay product.

Although the License Agreement purports to grant Par rights under the '100 patent and other unspecified current or future intellectual property (and a waiver of unspecified regulatory exclusivities), the parties provided no evidence that Concordia held any rights that might have prevented Par from selling generic Kapvay after expiration of the '100 patent. Aside from the '100 patent, which expired a week after the effective date of the license, no patent claiming Kapvay has ever been listed in the FDA Orange Book.

Par received final FDA approval for its generic Kapvay ANDA on September 30, 2013. It began selling generic Kapvay on October 7, 2013. Until May 15, 2015, Par was the only generic drug manufacturer to receive FDA approval for a generic Kapvay product.

Concordia launched an authorized generic Kapvay product in December 2014, after learning that the FTC was investigating its agreement with Par concerning Kapvay.

#### **Competitive Analysis**

The complaint charges that the challenged agreement between Par and Concordia constituted an unreasonable restraint of trade that was likely to harm competition and consumers by enabling Par to price its generic Kapvay product without facing competition from an authorized generic version of the drug. By agreeing to share a portion of its likely supra-competitive profits with Concordia, Par protected itself from competition from an authorized generic for five years. The agreement was not plausibly related to any efficiency-enhancing joint undertaking. It is therefore appropriate to analyze the challenged conduct here as a straightforward agreement not to compete.

The evidence in this case indicated that, without a competing generic Kapvay product, consumers and other private and public purchasers were likely forced to pay higher prices for generic Kapvay. In addition, as noted above, empirical evidence from the FTC's Authorized Generic Study confirms what economic theory predicts: when the brand company cedes all generic sales to the first generic entrant by agreeing not to introduce an authorized generic, the generic drug company on average captures substantially more sales and sells at significantly higher prices. Consumers, meanwhile, are forced to pay supra-competitive prices for the generic product.<sup>5</sup>

#### **The Proposed Orders**

The proposed orders are designed to remedy the unlawful conduct charged in the complaint and to prevent recurrence of similar conduct. The orders prohibit Par and Concordia from (1) enforcing the relevant provisions of their 2013 License Agreement and (2) entering into similar "no-authorized-generic" agreements in the future.

In the Par order, Paragraph II.A prohibits Par from seeking to enforce any provision in its 2013 License Agreement with Concordia that restricts Concordia's ability to market an authorized generic Kapvay product. Paragraph II.B provides that Par may not enter into any agreement that (1) limits a brand-name drug manufacturer's ability to market an authorized generic

<sup>5</sup> See Authorized Generic Report at vi, 41–48, 57–59.

<sup>2</sup> See *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005).

<sup>3</sup> Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* (2011) (hereinafter "Authorized Generic Study") at 41–48, available at <https://www.ftc.gov/reports/authorized-generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission>.

<sup>4</sup> Authorized Generic Study at iii.

version of a drug product for which Par is seeking FDA approval to sell a generic counterpart; and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question.<sup>6</sup>

In the Concordia order, Paragraph II requires Concordia to relinquish any and all rights to payment under the License Agreement and to provide written notice to Par and the FTC of that relinquishment. Paragraph III bars Concordia from entering any agreement with a generic applicant for a reference-listed drug for which Concordia holds the NDA, if the agreement (1) limits marketing of an authorized generic version of that drug and (2) the limitation extends beyond the expiration of any Orange-Book listed patents for the drug in question.

The proposed orders' prohibitions on future agreements limiting an authorized generic cover only agreements in which the restraint extends beyond patent expiration. Agreements to restrict the sale of an authorized generic sometimes appear in patent litigation settlements and can serve as a means of compensating the generic patent challenger for agreeing to stay off the market for a period of time.<sup>7</sup> These arrangements can raise the same antitrust concerns that the Supreme Court addressed in *FTC v. Actavis*, 133 S. Ct. 2223 (2013).<sup>8</sup> That is not this case, however, and the proposed orders are not designed to address that type of conduct. As discussed above, the challenged agreement here did not arise out of pending or threatened patent litigation and nearly the entire five-year term of the agreement covered the period after expiration of the Kapvay patent.

For purposes of these proposed orders, "authorized generic" means a drug product distributed by or on behalf of an NDA holder, but marketed as a generic, regardless of whether it is manufactured pursuant to an NDA, an ANDA, or a 505(b)(2) application.<sup>9</sup>

<sup>6</sup> This provision applies to actions taken on behalf of Par Pharmaceutical, Inc., and Par Pharmaceutical Holdings, Inc., but would not apply to conduct by Respondent TPG Partners VI, L.P. that is not taken on behalf of the Par entities.

<sup>7</sup> See, e.g., *Authorized Generic Study* at 139–53.

<sup>8</sup> See *King Drug Co. of Florence Inc. v. Smithkline Beecham Corp.*, No. 14–1243 (3rd Cir. June 26, 2015). See also Brief of Federal Trade Commission as Amicus Curiae, *American Sales Co. v. Warner-Chilcott Co., LLC*, Nos. 14–2071 and 15–1250 (1st Cir. June 16, 2015).

<sup>9</sup> A company seeking to market a generic product typically files an abbreviated new drug application (ANDA). In that case, instead of providing independent evidence of safety and effectiveness, the applicant must demonstrate that its drug is bioequivalent to its branded counterpart. In some circumstances, a generic drug manufacturer may

The proposed orders each include a notice provision designed to assist in monitoring the respondents' future conduct with respect to an agreement to restrict the sale of an authorized generic product—without regard to whether the agreement extends beyond expiration of any listed patent. Par is required to notify the Commission and provide certain specified information if it enters certain agreements with a party that markets a brand-name drug for which Par has filed an application to sell a generic equivalent. Covered agreements are those that (1) limit the sale of an authorized generic and (2) take effect before the expiration of all Orange-Book listed patents for the relevant brand-name drug. A comparable provision in the Concordia order requires Concordia to provide such notice for agreements with a party seeking FDA approval to market a generic version of a brand-name drug for which Concordia holds the NDA. Both notice provisions terminate ten years after issuance of the orders.

These notice provisions differ from the filing requirements contained in Section 1112 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The notice required by the orders must be filed at least 30 days prior to the effective date of the agreement; MMA filings must be made within ten days after execution of the agreement.

The proposed orders also require that for five years Par and Concordia maintain compliance programs with certain prescribed features. Finally, the proposed orders contain certain reporting and other provisions that are designed to assist the Commission in monitoring compliance and are standard provisions in Commission orders. The proposed orders will expire in 20 years.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 2015–21071 Filed 8–25–15; 8:45 am]

**BILLING CODE 6750–01–P**

need to submit reports of investigations of the safety and effectiveness of its product in addition to relying on existing data, under what is known as a "505(b)(2)" application.

## GENERAL SERVICES ADMINISTRATION

[Notice—MA–2015–04; Docket No. 2015–0002; Sequence 22]

### Federal Management Regulations; Improved Management of Undeliverable-as-Addressed Mail

**AGENCY:** Office of Government-Wide Policy, General Services Administration (GSA).

**ACTION:** Notice of a bulletin.

**SUMMARY:** The General Services Administration has issued Federal Management Regulation (FMR) Bulletin G–05, which provides guidance to Executive Branch agencies for improving management of undeliverable-as-addressed (UAA) mail. The bulletin provides agencies with information on the tools and best practices associated with UAA mail. The FMR Bulletin G–05 and all other FMR bulletins are located at <http://www.gsa.gov/fmrbulletins>.

**DATES:** *Effective Date:* August 26, 2015.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cynthia Patterson, Office of Government-wide Policy (MAF), Office of Asset and Transportation Management, General Services Administration, at 703–589–2641 or via email at [cynthia.patterson@gsa.gov](mailto:cynthia.patterson@gsa.gov). Please cite FMR Bulletin G–05.

**SUPPLEMENTARY INFORMATION:** FMR Bulletin G–05 consolidates information regarding tools and best practices for management of UAA mail from a number of sources. Better management of UAA mail reduces mailing costs and associated personnel costs, improves community outreach and relations, supports sustainability efforts by reducing printing, paper use, and energy consumption, and is consistent with the goals of Executive Orders 13589 and 13693, and the Federal Management Regulation. The four suggestions described in this bulletin are: (1) Establish internal policies to obtain and verify address correction, (2) prior to mailing, use USPS® certified vendors' address management tools, (3) actively manage returned mail with barcodes and scanning technology, and (4) track, monitor, and report returned mail on an annual basis to help the Federal community avoid UAA mail.

Dated: August 7, 2015.

**Christine Harada,**

*Associate Administrator, Office of Government-wide Policy, General Services Administration.*

[FR Doc. 2015–21187 Filed 8–25–15; 8:45 am]

**BILLING CODE 6820–14–P**