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.[6]

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.[7] These arrangements can raise the same antitrust concerns that the Supreme Court addressed in *FTC* v. *Actavis,* 133 S. Ct. 2223 (2013).[8] 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.[9]

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.

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[6] 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.

[7] *See, e.g.,* Authorized Generic Study at 139–53.

[8] *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).

[9] 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 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.* 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]

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