■ 8. Section 1309.25 is amended by adding a new paragraph (c) to read as follows:

§ 1309.25 Temporary exemption from registration for chemical registration applicants.

* * * * *

(c) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822 or 957) to obtain a registration to manufacture or import prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before March 3, 2010. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied the application. This exemption applies only to registration; all other chemical control requirements set forth in this part and parts 1310, 1313, and 1315 of this chapter remain in full force and effect.

Dated: January 22, 2010.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 2010–1968 Filed 1–29–10; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

28 CFR Part 0

[Docket No. DEA–315F]

Redelegation of Functions; Delegation of Authority to Drug Enforcement Administration Official

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: Under delegated authority, the Administrator of the Drug Enforcement Administration (DEA), Department of Justice, is amending the appendix to the Justice Department regulations to redelegate certain functions and authority which were vested in the Attorney General by the Controlled Substances Act and subsequently delegated to the Administrator of DEA.

DATES: *Effective Dates:* This Final Rule is effective February 1, 2010.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA, as amended, also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

Retail Sales Provisions of the Combat Methamphetamine Epidemic Act of 2005

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). Among other things, the CMEA amended the CSA to change the regulations for selling nonprescription products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. CMEA created a new category of products called scheduled listed chemical products. A scheduled listed chemical product is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug (21 U.S.C. 802(45)(A), 21 CFR 1300.02(b)(34)(i))).

CMEA established provisions regarding the retail sale of these scheduled listed chemical products by regulated sellers (i.e., retail distributors including mobile retail vendors) and distributors required to submit reports under 21 U.S.C. 830(b)(3) (*i.e.,* mail order distributors). These requirements, which were promulgated in 21 CFR, part 1314, include, but are not limited to:

- Packaging requirements for nonliquid forms of scheduled listed chemical products (*i.e.,* blister packs, with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches) (21 CFR 1314.05).
- Daily sales limits (21 CFR 1314.20).
- Product placement (i.e., placing the product so that customers do not have direct access before the sale is made, referred to as "behind the counter" placement, including circumstances in which the product is stored in a locked cabinet located in an area of the facility where customers do have direct access) (21 CFR 1314.25(b)).
- Recordkeeping (*i.e.,* logbook provisions) (21 CFR 1314.30).
- Employee training (21 CFR 1314.35).
- Self-certification (21 CFR 1314.40).

Redelegation of Authority

The Attorney General has delegated his functions under the CSA to the Administrator of the Drug Enforcement Administration (21 U.S.C. 871(a) and 28 CFR 0.100(b)). The Attorney General has also authorized the Administrator to redelegate any of his functions under the CSA to any subordinates (28 CFR 0.104). To further enhance the administration of the CSA and its regulations, the Administrator is redelegating to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, and the authority to exercise all necessary functions with respect to the promulgation and implementation of regulations in 21 CFR, part 1314. This redelegation will empower the Deputy Assistant Administrator, among other things, to exercise signing authority for any rules, regulations, or procedures which he may deem necessary for the efficient execution of the retail sales provisions contained in part 1314. Final orders in connection with the suspension or revocation of a regulated seller's or mail order distributor's right to sell scheduled listed chemical products shall continue to be made by the Deputy

Administrator of the Drug Enforcement Administration.

The redelegation of signature authority for the regulations in part 1314 is consistent with the signature authority already redelegated to the Deputy Assistant Administrator of the Office of Diversion Control pertaining to the promulgation of regulations related to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances and List I chemicals in parts 1301 and 1309, respectively (28 CFR Appendix to Subpart R, 7(a), 7(h)).

Regulatory Certifications

Congressional Review Act

The DEA has determined that this action pertains to DEA management and is a rule relating to DEA organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties, and, accordingly, is not a "rule" as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104–121). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Administrative Procedure Act

This rule redelegates signature authority for the promulgation of certain regulations related to the retail sale of scheduled listed chemical products from the Deputy Administrator of the DEA to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration. Since the rule relates to agency organization, procedure, or practice, it is excepted from the general notice requirements of the Administrative Procedure Act (5 U.S.C. 553(b) pursuant to 5 U.S.C. 553(b)(A). The redelegation of signature authority for the regulations in part 1314 is consistent with the signature authority already redelegated to the Deputy Assistant Administrator, Office of Diversion Control, pertaining to the promulgation of regulations related to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances and List I chemicals in parts 1301 and 1309, respectively (28 CFR Appendix to Subpart R, 7(a), 7(h)).

Further, the Administrative Procedure Act permits an agency to make this rule effective upon the date of publication as provided by the agency for good cause found and published with the rule (5 U.S.C. 553(d)(3)). As this rule merely redelegates signature authority for certain regulations and has no impact on regulated entities, DEA finds good cause to make this rule effective upon publication.

Regulatory Flexibility Act

The Acting Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). This rule will not have a significant economic impact on a substantial number of small entities because it pertains to administrative matters affecting the DEA. Further, a Regulatory Flexibility Analysis was not required to be prepared for this final rule because DEA was not required to publish a general notice of proposed rulemaking for this matter.

Executive Order 12866

The Acting Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). This rule is limited to agency organization, management and personnel as described by Executive Order 12866 section (3)(d)(3) and, therefore, is not a "regulation" or "rule" as defined by that Executive Order. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 28 CFR Part 0

Authority delegations (Government agencies), Government employees, Organizations and functions (Government agencies), Privacy, Reporting and recordkeeping requirements, Whistleblowing.

■ For the reasons set forth above, and pursuant to the authority vested in the Administrator of the Drug Enforcement Administration by 28 CFR 0.100 and 0.104, and 21 U.S.C. 871, 28 CFR, part 0 is amended as follows:

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

■ 1. The authority citation for part 0 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 509, 510, 515–519.

■ 2. Section 7 of the Appendix to subpart R is amended by adding a new paragraph (m) to read as follows:

Appendix to Subpart R of Part 0—Redelegation of Functions

* * * * *

Sec. 7. Promulgation of regulations.

* * * * *

(m) Part 1314, incident to the retail sale of scheduled listed chemical products by regulated sellers and distributors required to submit reports under section 310(b)(3) of the Act (21 U.S.C. 830(b)(3)), except that final orders in connection with suspension or revocation of the regulated seller's or mail order distributor's right to sell scheduled listed chemical products shall be made by the Deputy Administrator of the Drug Enforcement Administration.

* * * * *

Dated: January 21, 2010.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. 2010–1967 Filed 1–29–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9 and 721

[EPA–HQ–OPPT–2008–0918; FRL–8438–4]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is promulgating significant new use rules (SNURs) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for 15 chemical substances which were the subject of premanufacture notices (PMNs). Three of these chemical substances are subject to TSCA section 5(e) consent orders issued by EPA. This action requires persons who intend to manufacture,