

development. A summary of that consultation is provided in the docket for this rule (see EPA-HQ-RCKA-2008-0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

#### H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals*, found in the docket for this action.

#### I. Executive Order 13211: Energy Supply

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

#### J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

#### K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the *Regulatory Impact Analysis*, which can be found at [regulations.gov](http://regulations.gov) under docket number EPA-HQ-RCKA-2007-0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living

near and downstream from wastewater treatment plants may also benefit from the elimination of sewerage of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewerage expected under the final rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

#### L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 *et seq.*) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the Federal Register. A major rule cannot take effect until sixty (60) days after it is published in the Federal Register. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This final authorization will be effective August 22, 2019.

#### List of Subjects

##### 40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

##### 40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

##### 40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

##### 40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

##### 40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

##### 40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

##### 40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

##### 40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

Andrew K. Wheeler,  
Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

#### PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

§ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912(a), 6921, 6922, 6924(y) and 6938.

§ 2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

##### § 261.4 Exclusions.

(a) \* \* \*

(1) \* \* \*

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 268.505 and Clean Water Act requirements at 40 CFR 403.5(b). "Domestic sewage" means

untreated sanitary wastes that pass through a sewer system.

§ 3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

§ 4. Section 261.33 is amended by:  
 a. Revising paragraph (c); and  
 b. Revising the four entries for "P075" in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[Comment: Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or

being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

(e) \* \* \*

Hazardous waste No.	Chemical abstracts No.	Substance
P075	154-11-5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
P075	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
P075	154-11-5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
P075	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

§ 5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922-6925, 6937, 6938, and 6939g.

§ 6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the

management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land

or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

§ 7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

<sup>1</sup> CAS Number given for parent compound only.