

US EPA ARCHIVE DOCUMENT

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(9) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium (Actinomyces) pyogenes</i> ; and for suppression of estrus (heat).	Feed continuously to heifers during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. See §§ 558.342(d), 558.355(d), and 558.625(c). Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter. Withdrawal period: 3 days.	000061

Dated: April 3, 2015.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
 [FR Doc. 2015-08025 Filed 4-7-15; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2015-N-0002]

Implantation or Injectable Dosage Form New Animal Drugs; Withdrawal of Approval of New Animal Drug Application; Fomepizole

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) for a fomepizole injectable solution used as an antidote for ethylene glycol poisoning in dogs. This action is being taken at the sponsor's request because this product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective April 20, 2015.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9075, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904 has requested that FDA withdraw approval of NADA 141-075 for ANTIZOL-VET (fomepizole) Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 141-075, and all supplements and amendments thereto, is hereby withdrawn.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: April 3, 2015.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
 [FR Doc. 2015-08024 Filed 4-7-15; 8:45 am]
BILLING CODE 4164-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260 and 261

[EPA-HQ-RCRA-2015-0118; FRL_9923-12-OSWER]

Response to Vacaturs of the Comparable Fuels Rule and the Gasification Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is revising regulations associated with the comparable fuels exclusion and the gasification exclusion, originally issued by EPA under the Resource Conservation and Recovery Act (RCRA). These revisions implement vacaturs ordered by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), on June 27, 2014.

DATES: Effective April 8, 2015.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-RCRA-2015-0118. All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the EPA Docket Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m. Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the RCRA Docket is (202) 566-0270.

FOR FURTHER INFORMATION CONTACT: Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, MC 5304P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460, Tracy Atagi, at (703) 308-8672, (atagi.tracy@epa.gov) or Frank Behan, at (703) 308-8476, behan.frank@epa.gov.

SUPPLEMENTARY INFORMATION:

Preamble Outline

- I. General Information
- II. Statutory Authority
- III. Which regulations is EPA removing?
- IV. Background on the Comparable Fuels Rule and the Gasification Rule
- V. When will the final rule become effective?
- VI. State Authorization
- VII. Statutory and Executive Order (EO) Reviews

I. General Information

A. Does this action apply to me?

Today's final rule applies to generators, transporters, and facilities treating, storing, disposing or otherwise managing hazardous wastes previously excluded from RCRA regulation under the comparable fuels rule or previously excluded from RCRA regulation under the gasification rule. EPA has not identified any entities currently operating under the gasification rule, but has identified 31 facilities that appear to be managing previously-excluded comparable fuels. A list of these facilities is available in the docket for today's rule (Docket ID no. EPA-HQ-RCRA-2015-0118).

B. Why is EPA issuing a final rule?

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(3)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for removing these provisions without prior proposal and opportunity for comment, because these revisions are consistent with court orders vacating these rules. As a matter of law, the orders issued by the United States Court of Appeals for the District of Columbia Circuit on June 27, 2014, vacated the "comparable fuels rule" and the gasification rule issued by EPA under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6901, *et seq.* It is, therefore, unnecessary to provide notice and an opportunity for comment on this action, which merely carries out the court's orders. For the same reasons, EPA finds that it has good cause to make the revisions effective under 5 U.S.C. 553(d) and section 3010(b) of RCRA 42 U.S.C. 6930(b).

II. Statutory Authority

These regulations are promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3006, 3007, 3010, and 3017 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924. This statute is commonly referred to as "RCRA."

III. Which regulations is EPA removing?

EPA is removing provisions at 40 CFR 261.4(a)(16) and 40 CFR 261.38 related to comparable fuels, and revising 40 CFR 261.4(a)(12)(i) by removing gasification from the list of specific petroleum refining processes into which oil-bearing hazardous secondary materials may be inserted. The effect of the removal of 40 CFR 261.4(a)(16) and 261.38 will be to make comparable fuels that were previously excluded from the RCRA definition of solid waste subject to regulation under RCRA subtitle C. The removal of gasification from 40 CFR 261.4(a)(12)(i) will prevent hazardous secondary materials generated at petroleum refineries from being inserted into gasifiers at refineries without being deemed hazardous wastes and therefore being subject to hazardous waste regulations under RCRA subtitle C. As a result of these previously excluded materials now being identified as hazardous waste under 40 CFR 261.3, facilities burning these materials will be subject to regulation as Hazardous Waste Combustors under 40 CFR part 63 subpart EEE, as well as applicable regulations under RCRA subtitle C.

IV. Background on the Comparable Fuels Rule and the Gasification Rule

A. The Comparable Fuels Rule

EPA promulgated the Comparable Fuels Rule in 1998.¹ The rule provided that fuels made from materials identified as hazardous wastes were excluded from the RCRA definition of solid waste if, as generated or after treatment and blending, they were sufficiently comparable to commercial fossil fuels for which they were substituted with respect to levels of hazardous constituents and physical properties that affect fuel burning efficiency, such as viscosity and heating value. Because the fuels, as burned, would contain contaminants no greater than commercial fossil fuels, and were otherwise indistinguishable from the fossil fuels that would be burned in their place, EPA found that the comparable fuels would pose no greater risk than commercial fuels when burned, and could be legitimately classified as non-waste fuels rather than as solid and hazardous waste fuels.

The Agency took the position that comparable fuels were not being "discarded" within the meaning of the definition of solid waste in RCRA section 1004(27), 42 U.S.C. 6903(27). RCRA defines solid wastes, for relevant

purposes, as materials that have been discarded in the plain sense of the term, meaning that the material has been thrown away, disposed of or abandoned. Under RCRA a material regulated as a hazardous waste must first be a solid waste—that is, a discarded material. Thus, even though the comparable fuels were derived from materials that are listed hazardous wastes, EPA had concluded that fuels that met specified comparability criteria were not solid wastes because they looked no different from commercial fuels.

The comparable fuels rule was vacated by United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), on June 27, 2014 (*Natural Resources Defense Council v. EPA*, 755 F. 3d 1010 (June 27, 2014)). In its decision, the court held that the unambiguous language of section 3004(q) requires that fuels produced from hazardous wastes must remain classified as hazardous wastes under subtitle C (other than in limited specified instances not relevant here). Section 3004(q), according to the court, unequivocally provides that EPA "shall" promulgate regulations as "may" be necessary to protect human health and the environment for the production of fuels from "any" materials identified as hazardous waste under RCRA. All hazardous secondary materials from which the comparable fuels were made were identified in RCRA regulations as hazardous wastes.

On November 3, 2014, the court granted EPA's motion to stay the issuance of the mandate for the comparable fuels rule until March 30, 2015, in order to allow affected facilities time to come into compliance with applicable subtitle C regulations.

B. Gasification Rule

Under the gasification rule, which was promulgated in 2008,² EPA determined that oil-bearing hazardous secondary materials, even though otherwise identified as hazardous wastes under RCRA if discarded, are not in fact discarded and not solid wastes if they are inserted into a gasification unit located at a petroleum refinery to produce synthesis gas.³ Therefore, they were excluded from hazardous waste regulation.

The gasification rule was vacated by United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit), on June 27, 2014. (*Sierra Club*

² See "Regulation of Oil-Bearing Hazardous Secondary Materials From the Petroleum Refining Industry Processed in a Gasification System To Produce Synthesis Gas," 73 FR 57-72 (Jan. 2, 2008).

³ Synthesis gas is a type of fuel that may be burned for the recovery of energy.

¹ See "Hazardous Waste Combustors; Revised Standards," 63 FR 33782 (June 19, 1998).

v. *EPA*, 755 F. 3d 968). The court held, similar to its decision on the Comparable Fuels Rule, that the Gasification Rule violates the plain language of RCRA section 3004(q) because fuels produced from hazardous wastes remain solid and hazardous wastes. Thus, all hazardous wastes inserted into a gasification unit at petroleum refineries remain subject to RCRA regulations as hazardous wastes.

The court issued its mandate for the vacatur of the gasification rule on November 3, 2014.

V. When will the final rule become effective?

The removal of the comparable fuels exclusion and the revisions removing gasification as an exclusion are effective immediately.

VI. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize a qualified state to administer and enforce a hazardous waste program within the state in lieu of the federal program, and to issue and enforce permits in the state. A state may receive authorization by following the approval process described in 40 CFR 271.21 (see 40 CFR part 271 for the overall standards and requirements for authorization). EPA continues to have independent authority to bring enforcement actions under RCRA sections 3007, 3008, 3013, and 7003. An authorized state also continues to have independent authority to bring enforcement actions under state law.

After a state receives initial authorization, new federal requirements promulgated under RCRA authority existing prior to the 1984 Hazardous and Solid Waste Amendments (HSWA) do not apply in that state until the state adopts and receives authorization for equivalent state requirements. In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), new federal requirements and prohibitions imposed under subtitle C pursuant to HSWA provisions take effect in authorized states at the same time that they take effect in unauthorized states. As such, EPA carries out the HSWA requirements and prohibitions in authorized states, including the issuance of new permits implementing those requirements, until EPA authorizes the state to do so.

Authorized states are required to modify their programs only when EPA enacts federal requirements that are more stringent or broader in scope than the existing federal requirements. RCRA section 3009 allows the states to impose

standards more stringent than those in the federal program (see also 40 CFR 271.1(i)). Therefore, authorized states are not required to adopt federal regulations that are considered less stringent than previous federal regulations or that narrow the scope of the RCRA program. Previously authorized hazardous waste regulations would continue to apply in those states.

B. Effect on State Authorization of D.C. Circuit Court Vacaturs

On March 30, 2015, the D.C. Circuit Court issued its mandate, effectuating the vacatur of the comparable fuels rule, as described earlier in this document. The mandate for the gasification rule was issued on November 3, 2014. The court's vacaturs mean that these federal rules are legally null and void. Therefore, the court's mandates reinstate the regulatory status of the materials previously in effect as if the vacated rules never existed. Because excluded comparable fuels and gasified hazardous waste were, or would have been, previously regulated as discarded solid waste, these materials, if hazardous, must be handled as hazardous waste in compliance with requirements applicable to the generation, transportation, treatment, storage, or disposal of hazardous waste after March 30, 2015. At the federal level, because the effect of the vacaturs means, in essence, that these rules should not have been promulgated, this document simply removes them from the exclusions in the federal regulations. At the state level, because no state rules were challenged in the litigation, the court decision does not affect any state exclusions. However, the vacaturs do have an impact on the authorization status of states. The multiple scenarios that exist in the states are discussed below.

1. States Without Final RCRA Authorization

For states that have no RCRA authorization status (Iowa, Alaska), the vacaturs simply mean that the federal rules will no longer be in effect in those states and by this document, EPA is alerting interested parties of the removal of the vacated rules from the Code of Federal Regulations. The subject materials are federally regulated and EPA may bring enforcement actions under RCRA Section 3008 at facilities that do not comply with the RCRA hazardous waste regulations. The state programs are completely unaffected by the vacaturs and these states do not have to modify their programs in any way regardless of how they currently regulate the materials.

2. States That Have Final Authorization but Did Not Promulgate Similar Rules

For states that have been authorized under RCRA but did not adopt rules similar to the comparable fuels and gasification rules (and therefore were not authorized for them), there were no federal comparable fuels and gasification rules in effect prior to vacatur because the federal comparable fuels and gasification rules were less stringent than the federal hazardous waste regulations and states were not required to adopt or become authorized for these rules. Therefore, these vacaturs will have no effect on the authorization status in these states. The subject materials remain regulated under the authorized state hazardous waste program and EPA may continue to bring enforcement actions under RCRA Section 3008 at facilities that do not comply with the RCRA hazardous waste regulations. These states do not have to modify their programs.

3. States That Adopted Similar Rules But Are Not Yet Authorized for Them

For states that have adopted similar rules but have not yet been authorized for them, the vacatur of the federal rules will not change the authorization status of the state programs. The authorization status that was established prior to the adoption of the state counterpart rules remains in effect and EPA may continue to bring enforcement actions under RCRA Section 3008 at facilities that do not comply with the RCRA hazardous waste regulations. The vacaturs and subsequent removal of the federal rules will result in state programs that are less stringent than the federal program as long as state provisions that exclude the subject materials from regulation remain in effect in the state programs. EPA encourages these states to expeditiously remove these rules from their programs.

4. States That Adopted Similar Rules and Have Been Authorized for Them

For states that have previously been authorized for the comparable fuels and gasification rules, the effect of the vacaturs is that the previously authorized comparable fuels and gasification rules from the state program will no longer be considered part of the federally authorized program. Thus, EPA may bring enforcement actions under RCRA Section 3008 at facilities that do not comply with the RCRA hazardous waste regulations. In other words, the authorization status of the state program that was in place prior to authorization of the state comparable fuels and gasification rules is reinstated with regard to these rules. EPA strongly

encourages these states to proceed expeditiously to remove these counterpart rules. Once the counterpart rules are removed, these states should notify their EPA regional office by letter to verify the status of the state program.

VII. Statutory and Executive Order (EO) Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993) and Executive Order 13563 (76 FR 3821, January 21, 2011), this action is not a “significant regulatory action” and is therefore not subject to OMB review. Because this action is not subject to notice and comment requirements under the Administrative Procedures Act or any other statute, it is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) or Sections 202 and 205 of the Unfunded Mandates Reform Act of 1999 (UMRA) (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments. This action does not create new binding legal requirements that substantially and directly affect Tribes under Executive Order 13175 (65 FR 67249, November 9, 2000). This action does not have significant Federalism implications under Executive Order 13132 (64 FR 43255, August 10, 1999). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This action does not involve technical standards; thus, the requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before certain actions may take effect, the agency promulgating the action must submit a report, which includes a copy of the action, to each House of the Congress and to the

Comptroller General of the United States. This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Solid Waste.

Dated: April 1, 2015.

Mathy Stanislaus,

Assistant Administrator, Office of Solid Waste and Emergency Response.

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

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

- 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939 and 6974.

Subpart B—Definitions

§ 260.10 [Amended]

- 2. Section 260.10 is amended by removing the definition of “Gasification.”

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

- 3. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

- 4. Section 261.4 is amended by revising paragraph (a)(12)(i), and removing and reserving paragraph (a)(16) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(12)(i) Oil-bearing hazardous secondary materials (*i.e.*, sludges, byproducts, or spent materials) that are generated at a petroleum refinery (SIC code 2911) and are inserted into the petroleum refining process (SIC code 2911—including, but not limited to, distillation, catalytic cracking, fractionation, or thermal cracking units

(*i.e.*, cokers)) unless the material is placed on the land, or speculatively accumulated before being so recycled. Materials inserted into thermal cracking units are excluded under this paragraph, provided that the coke product also does not exhibit a characteristic of hazardous waste. Oil-bearing hazardous secondary materials may be inserted into the same petroleum refinery where they are generated, or sent directly to another petroleum refinery and still be excluded under this provision. Except as provided in paragraph (a)(12)(ii) of this section, oil-bearing hazardous secondary materials generated elsewhere in the petroleum industry (*i.e.*, from sources other than petroleum refineries) are not excluded under this section. Residuals generated from processing or recycling materials excluded under this paragraph (a)(12)(i), where such materials as generated would have otherwise met a listing under subpart D of this part, are designated as F037 listed wastes when disposed of or intended for disposal.

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(16) [Reserved]

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§ 261.38 [Removed and Reserved]

- 5. Remove and reserve § 261.38.

[FR Doc. 2015–07992 Filed 4–7–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1991–0006; FRL–9925–83–Region 8]

National Oil and Hazardous Substances Pollution Contingency Plan National Priorities List: Deletion of the Midvale Slag Superfund Site

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Region 8 announces the deletion of the Midvale Slag Superfund Site (Site), located in Salt Lake County, Utah, from the National Priorities List (NPL). The NPL, promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the State of Utah, through the Utah Department of Environmental Quality (UDEQ), have determined that all