

Containing Natural Health Products—Assessing the Potential Risk of Liver Injury (Hepatotoxicity),” December 12, 2017. Available at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/green-tea-extract-containing-natural-health-products-assessing-potential-risk-liver-injury.html>.

26. *FDA Import Alert 54–07. Available at https://www.accessdata.fda.gov/cms_ia/importalert_139.html.
27. Garon, E.B., et al. “Dichloroacetate Should be Considered with Platinum-based Chemotherapy in Hypoxic Tumors Rather Than as a Single Agent in Advanced Non-small Cell Lung Cancer,” *Journal of Cancer Research and Clinical Oncology*, 140:443, 2014.
28. Shoemaker, R.C., et al. “Vasoactive Intestinal Polypeptide (VIP) Corrects Chronic Inflammatory Response Syndrome (CIRS) Acquired Following Exposure to Water-Damaged Buildings,” *Health*, 5:396–401, 2013. Available at <https://www.scrip.org/journal/health/>. (Open Access)
29. *Amendments to the List of Bulk Drug Substances that Can be Used to Compound Drug Products in Accordance with Section 503A of the Federal Food, Drug, and Cosmetic Act, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, 2018. Available at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects in 21 CFR Part 216

Drugs, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 216 be amended as follows:

PART 216—HUMAN DRUG COMPOUNDING

- 1. The authority citation for part 216 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353a, 353b, 355, and 371.

- 2. In § 216.23, revise paragraphs (a) and (b) to read as follows:

§ 216.23 Bulk drug substances that can be used to compound drug products in accordance with section 503A of the Federal Food, Drug, and Cosmetic Act.

(a) The following bulk drug substances, which are neither the subject of a current applicable United States Pharmacopeia or National Formulary monograph nor components of FDA-approved drugs, can be used in compounding under section 503A(b)(1)(A)(i)(III) of the Federal Food, Drug, and Cosmetic Act.

- (1) Brilliant Blue G, also known as Coomassie Brilliant Blue G–250.
- (2) Cantharidin (for topical use only).
- (3) Diphenylcyclopropenone (for topical use only).
- (4) Glutaraldehyde (for topical use only, in concentrations of 10 percent or lower).
- (5) Glycolic acid (for topical use only, in concentrations of 70 percent or lower).
- (6) L-citrulline (for oral administration only).
- (7) N-acetyl-D-glucosamine (for topical use only).
- (8) Pyruvic acid (for topical use only).
- (9) Squaric acid dibutyl ester (for topical use only).
- (10) Thymol iodide (for topical use only).
- (11) Trichloroacetic acid (for topical use only).
- (b) The following bulk drug substances have been nominated and evaluated for inclusion on the list of substance that can be used in compounding set forth in paragraph (a) of this section, and FDA has determined that they do not meet the criteria for inclusion set forth in paragraph (c) of this section:
 - (1) 7-keto dehydroepiandrosterone (DHEA).
 - (2) Acetyl L Carnitine.
 - (3) Alanine L Glutamine.
 - (4) Aloe Vera 200:1 Freeze Dried.
 - (5) Artemisinin.
 - (6) Astragalus extract 10:1.
 - (7) *Boswellia*.
 - (8) Cesium Chloride.
 - (9) Chondroitin Sulfate.
 - (10) Chrysin.
 - (11) Curcumin.
 - (12) D-Ribose.
 - (13) Deoxy-D-Glucose.
 - (14) Diindolylmethane.
 - (15) Domperidone.
 - (16) Epigallocatechin gallate (EGCG).
 - (17) Germanium Sesquioxide.
 - (18) Glycyrrhizin.
 - (19) Kojic acid.
 - (20) Nettle.
 - (21) Nicotinamide adenine dinucleotide (NAD).
 - (22) Nicotinamide adenine dinucleotide disodium reduced (NADH).
 - (23) Oxtripitan.
 - (24) Piracetam.
 - (25) Rubidium Chloride.
 - (26) Silver Protein Mild.
 - (27) Sodium dichloroacetate.
 - (28) Tranilast.
 - (29) Vanadyl sulfate.
 - (30) Vasoactive intestinal peptide.

* * * * *

Dated: July 16, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: August 13, 2019.

Eric D. Hargan,

Deputy Secretary, Department of Health and Human Services.

[FR Doc. 2019–18951 Filed 9–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH–262–FOR; Docket ID: OSM–2019–0006
S1D1S SS08011000 SX064A000
190S180110; S2D2S SS08011000
SX064A000 19XS501520]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSMRE), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Ohio regulatory program, hereinafter the Ohio program, under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Ohio seeks to amend its program by revising a definition involving the transfer, assignment, or sale of permit rights. This document gives the times and locations that the Ohio program and this proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments, on the amendment and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this request until 4:00 p.m., Eastern Standard Time (e.s.t.), October 7, 2019. If requested, we will hold a public hearing on the request on September 30, 2019. We will accept requests to speak at a hearing until 4:00 p.m., e.s.t. on September 20, 2019.

ADDRESSES: You may submit comments, identified by SATS No. OH–262–FOR, Docket ID: OSM–2019–0006, by any of the following methods:

- *Mail/Hand Delivery:* Mr. Ben Owens, Chief, Pittsburgh Field Division Office of Surface Mining Reclamation and Enforcement 3 Parkway Center, Pittsburgh, Pa 15220.

• *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Public Comment Procedures” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Ohio program, this request, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the request by contacting OSMRE’s Pittsburgh Field Division or the full text of the request is available for you to read at www.regulations.gov.

Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2827, Email: bowens@osmre.gov.

In addition, you may review a copy of the request during regular business hours at the following location:

Mr. Larry E. Erdos, Chief, Division of Mineral Resources Management, Ohio Department of Natural Resources, 2045 Morse Rd., Building H-2, Columbus, OH 43229-6693, Telephone: (614) 265-6633, Email: lanny.erdos@dnr.state.oh.us.

FOR FURTHER INFORMATION CONTACT: Mr. Ben Owens, Chief, Pittsburgh Field Division, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2827, Email: bowens@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Ohio Program
- II. Description of the Request
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Ohio Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, State laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis

of these criteria, the Secretary of the Interior conditionally approved the Ohio program on August 16, 1982. You can find additional background information on the Ohio program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the August 10, 1982, **Federal Register**, 47 FR 34688. You can also find later actions concerning Ohio’s program and program amendments at 30 CFR 935.11 and 935.15.

II. Description of the Request

By letter dated April 11, 2019, Ohio sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) that involves the regulatory definition of “transfer, assignment, or sale of permit rights” related to coal mining operations (Administrative Record No. OH-2198). Ohio seeks to add regulatory language at Chapter 1501:13-1-02, *Definitions*, section (VVVVVV) of the Ohio Administrative Code, which currently defines the term as “a change of a permittee, including, but not limited to, any fundamental legal change in the structure or nature of a permittee, or a name change.” With this amendment, Ohio seeks to expand the definition to include a change in the ownership and operational control of a permittee to a person who has not held a permit issued under Chapter 1513, *Coal Surface Mining*, of the Ohio Revised Code (ORC) for a period of not less than five years where the existence and name of the permittee remain the same. Ohio states that this change is intended to prevent a person who is not eligible to participate in the bond pool under section 1513.08(C)(2) of the ORC from gaining access to the bond pool through a change of ownership and operational control that does not change the existence and name of the permittee. Ohio states that requiring such a person to apply for a transfer, assignment, or sale of permit rights will assure that all performance security requirements are met.

The full text of the amendment is available for you to read at the locations listed above under **ADDRESSES** or at www.regulations.gov.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether this amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State program.

Electronic or Written Comments

If you submit written or electronic comments on the request during the 30-day comment period, they should be specific, confined to issues pertinent to the request, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence our decision will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., e.s.t. on September 20, 2019. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after everyone scheduled to speak, and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory

Affairs in the Office of Management and Budget (OMB) will review all significant rules. Pursuant to OMB guidance, dated October 12, 1993, the approval of State program amendments is exempted from OMB review under Executive Order 12866. Executive Order 13563, which reaffirms and supplements Executive Order 12866, retains this exemption.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to publish a notice in the **Federal Register** indicating receipt of the proposed amendment, its text or a summary of its terms, and an opportunity for public comment. We conclude our review of the proposed amendment after the close of the public

comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 4, 2019.

Thomas D. Shope,

Regional Director, Appalachian Region.

[FR Doc. 2019–19163 Filed 9–4–19; 8:45 am]

BILLING CODE 4310–05–P