

requests for records under the Freedom of Information Act, and requests for correction or amendment under the Privacy Act. 5 U.S.C.(d)(3).

Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

**List of Subjects in 15 CFR Part 4**

Freedom of information, Privacy.

■ For the reasons above, amend 15 CFR Part 4 as follows:

**PART 4—DISCLOSURE OF GOVERNMENT INFORMATION**

■ 1. The authority citation for Part 4 continues to read as follows:

**Authority:** 5 U.S.C. 301; 5 U.S.C. 552; 5 U.S.C. 552a; 5 U.S.C. 553; 31 U.S.C. 3717; 44 U.S.C. 3101; Reorganization Plan No. 5 of 1950.

**Appendix B to Part 4—[Amended]**

■ 2. In Appendix B to part 4, under the heading **ECONOMICS AND STATISTICS ADMINISTRATION**, delete “Bureau of the Census: Manager, Freedom of Information Act” and replace with “Bureau of the Census: Freedom of Information Act Officer”.

Dated: June 28, 2007.

**Brenda Dolan,**

*Departmental Freedom of Information and Privacy Act Officer.*

[FR Doc. E7–13001 Filed 7–3–07; 8:45 am]

**BILLING CODE 3510–07–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 524**

**New Animal Drugs; Change of Sponsor’s Name; Liquid Crystalline Trypsin, Peru Balsam, Castor Oil**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor’s name from Mylan Bertek Pharmaceuticals, Inc., to UDL Laboratories, Inc.

**DATES:** This rule is effective July 5, 2007.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Mylan Bertek Pharmaceuticals, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478, has informed FDA that it has changed its name to UDL Laboratories, Inc., and is using a new drug labeler code. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes. A conforming change is being made in 21 CFR 524.2620 for this sponsor’s sole product.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

**List of Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*21 CFR Part 524*

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 524 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Mylan Bertek Pharmaceuticals, Inc.” and alphabetically add a new entry for “UDL Laboratories, Inc.”; and in the table in paragraph (c)(2) remove the entry for “062749” and numerically add a new entry for “051079” to read as follows:

**§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.**

Firm name and address	Drug labeler code
* * * * *	* * * * *
(c) * * *	* * *
(1) * * *	* * *
* * * * *	* * * * *

Firm name and address	Drug labeler code
UDL Laboratories, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478.	051079
* * * * *	* * * * *
(2) * * *	* * *
Drug labeler code	Firm name and address
* * * * *	* * * * *
051079	UDL Laboratories, Inc., 12720 Dairy Ashford, Sugar Land, TX 77478
* * * * *	* * * * *

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for 21 CFR part 524 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 524.2620 [Amended]**

■ 4. In paragraph (a)(2) of § 524.2620, remove “062794” and add in its place “051079”.

Dated: June 21, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine.*

[FR Doc. E7–13010 Filed 7–3–07; 8:45 am]

**BILLING CODE 4160–01–S**

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 946**

**[VA–123–FOR]**

**Virginia Regulatory Program**

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

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We are approving an amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Virginia is revising its remaining regulations to make three of those provisions permanent by deleting a termination date of September 30, 2004, from the regulations. The amendment is intended to render the State regulations consistent with recent amendments to SMCRA.

**EFFECTIVE DATE:** July 5, 2007.

**FOR FURTHER INFORMATION CONTACT:** Mr. Tim Dieringer, Director, Knoxville Field Office; Telephone: (276) 523-4303. Internet: [tdieringer@osmre.gov](mailto:tdieringer@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Virginia Program
- II. Submission of the Amendment
- III. OSM's Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision
- VI. Procedural Determinations

**I. Background on the Virginia 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 program includes, among other things, “\* \* \* a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Virginia program on December 15, 1981. You can find background information on the Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Virginia program in the December 15, 1981, **Federal Register** (46 FR 61088). You can also find later actions concerning Virginia's program and program amendments at 30 CFR 946.12, 946.13, and 946.15.

**II. Submission of the Amendment**

By letter dated February 13, 2007 (Administrative Record Number VA-1058), the Virginia Department of Mines, Minerals and Energy (DMME) submitted an amendment to the Virginia program. In its letter, the DMME stated that the program amendment revises the Virginia Coal Surface Mining Reclamation Regulations to reflect the deletion from SMCRA, at section 510(e), of the termination date of section 510(e) of September 30, 2004.

Section 510 of SMCRA concerns permit approval or denial. Subsection 510(e) provides an exception to the prohibition of subsection (c), which prohibits the issuance of a permit where any surface coal mining operation owned or controlled by an applicant is currently in violation of SMCRA or such other laws referenced at subsection 510(c). Prior to being amended by the Tax Relief and Health Care Act of 2006, subsection 510(e) provided as follows:

(e) After the date of enactment of this subsection, the prohibition of subsection (c)

shall not apply to a permit application due to any violation resulting from an unanticipated event or condition at a surface coal mining operation on lands eligible for remaining under a permit held by the person making such application. As used in this subsection, the term “violation” has the same meaning as such term has under subsection (c). The authority of this subsection and section 515(b)(20)(B) shall terminate on September 30, 2004.

The effect of the deletion of the termination date in the SMCRA provision quoted above (the entire last sentence was deleted) is twofold: (1) It makes permanent the authority at subsection 510(e) of SMCRA to approve a permit application for surface coal mining operations on lands eligible for remaining notwithstanding the existence of a violation resulting from an unanticipated event or condition at the site, and (2) it makes permanent the two-year revegetation responsibility period for lands eligible for remaining at subsection 515(b)(20)(B) of SMCRA.

In its amendment, Virginia is deleting the termination date of September 30, 2004, from three of its program regulations concerning remaining.

We announced receipt of the proposed amendment in the April 9, 2007, **Federal Register** (72 FR 17449). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on May 4, 2007. No comments were received.

**III. OSM's Findings**

1. 4 VAC 25-130-785.25. Lands eligible for remaining.

This provision is amended by deleting subsection (c) in its entirety. Currently, 4 VAC 25-130-785.25 provides as follows:

(a) This section contains permitting requirements to implement 4 VAC 25-130-773.15(b)(4). Any person who submits a permit application to conduct a surface coal mining operation on lands eligible for remaining must comply with this section.

(b) Any application for a permit under this section shall be made according to all requirements of this subchapter applicable to surface coal mining and reclamation operations. In addition, the application shall:

(1) To the extent not otherwise addressed in the permit application, identify potential environmental and safety problems related to prior mining activity at the site and that could be reasonably anticipated to occur. This identification shall be based on a due diligence investigation which shall include visual observations at the site, a record review of past mining at the site, and environmental sampling tailored to current site conditions.

(2) With regard to potential environmental and safety problems referred in subdivision (b)(1) of this section, describe the mitigative measures that will be taken to ensure that the applicable reclamation requirements of this chapter can be met.

(c) The requirements of this section shall not apply after September 30, 2004.

In its submittal letter, the DMME stated that the deletion of subsection (c) containing the termination date of September 30, 2004, is intended to reflect the deletion of that same termination date at subsection 510(e) of SMCRA.

We find that the deletion of the termination date of September 30, 2004, renders 4 VAC 25-130-785.25 consistent with and no less stringent than § 510(e) of SMCRA and can be approved.

2. 4 VAC 25-130-816.116(c)(2)(ii) and 817.116(c)(2)(ii). Revegetation; standards for success.

These provisions are amended by deleting the phrase “included in permits issued before September 30, 2004, or any renewals thereof” at the end of the first sentence in subparts (c)(2)(ii). Currently, 4 VAC 25-130-816.116(c) and 817.116(c) provide as follows:

(c) (1) The period of extended responsibility for successful revegetation shall begin after the last year of augmented seeding, fertilizing, irrigation, or other work, excluding husbandry practices that are approved by the division in accordance with subdivision (c)(3) of this section.

(2) The period of responsibility shall continue for a period of not less than:

(i) Five full years except as provided in subdivision (c)(2)(ii) of this section. The vegetation parameters identified in subsection (b) of this section for grazing land or pastureland and cropland shall equal or exceed the approved success standard during the growing seasons of any two years of the responsibility period, except the first year. Areas approved for the other uses identified in subsection (b) of this section shall equal or exceed the applicable success standard during the growing season of the last year of the responsibility period.

(ii) Two full years for lands eligible for remaining included in permits issued before September 30, 2004, or any renewals thereof. To the extent that the success standards are established by subdivision (b)(5) of this section, the lands shall equal or exceed the standards during the growing season of the last year of the responsibility period.

(3) The division may approve selective husbandry practices, excluding augmented seeding, fertilization, or irrigation, without extending the period of responsibility for revegetation success and bond liability, if such practices can be expected to continue as part of the postmining land use or if discontinuance of the practices after the liability period expires will not reduce the probability of permanent revegetation success. Approved practices shall be normal

conservation practices within the region for unmined lands having land uses similar to the approved postmining land use of the disturbed area, including such practices as disease, pest, and vermin control; and any pruning, reseeding and/or transplanting specifically necessitated by such actions.

In its submittal letter, the DMME stated that the deletion of the September 30, 2004, termination date at subparts (c)(2)(ii) is intended to reflect the deletion of that same termination date at subsection 510(e) of SMCRA.

We find that the deletion of the termination date of September 30, 2004, renders 4 VAC 25–130–816.116(c)(2)(ii) and 817.116(c)(2)(ii) consistent with and no less stringent than § 510(e) of SMCRA and can be approved.

#### IV. Summary and Disposition of Comments

##### *Public Comments*

We asked for public comments on the amendment (Administrative Record Number VA–1068) and no comments were received.

##### *Federal Agency Comments*

Under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, on February 22, 2007, we requested comments on the amendments from various Federal agencies with an actual or potential interest in the Virginia program (Administrative Record Number VA–1060). The United States Department of the Interior, Bureau of Land Management responded and stated that they found no inconsistencies with the proposed changes and the Federal Laws, which govern mining. The United States Department of Labor, Mine Safety and Health Administration responded and stated that there did not seem to be any conflicts with the changes and deemed the changes appropriate. The United States Department of the Interior, Fish and Wildlife Service responded and stated that no impacts to Federally listed or proposed species or Federally designated critical habitat will occur and was in agreement with the changes made.

##### *Environmental Protection Agency (EPA) Concurrence and Comments*

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Virginia proposed to make in this amendment pertain to air or water quality standards. Therefore, we

did not ask EPA to concur on the amendment.

Under 30 CFR 732.17(h)(II)(i), we requested comments on the amendment from the EPA (Administrative Record number VA–1060). No comments were received.

#### V. OSM's Decision

Based on the above findings, we are approving the amendment sent to us by Virginia on February 13, 2007. To implement this decision, we are amending the Federal regulations at 30 CFR part 946, which codify decisions concerning the Virginia program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that the State's program demonstrate that the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

#### VI. Procedural Determinations

##### *Executive Order 12630—Takings*

The provisions in the rule based on counterpart Federal regulations do not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations. The revisions made at the initiative of the State that do not have Federal counterparts have also been reviewed and a determination made that they do not have takings implications. This determination is based on the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

##### *Executive Order 12866—Regulatory Planning and Review*

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

##### *Executive Order 12988—Civil Justice Reform*

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10),

decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

##### *Executive Order 13132—Federalism*

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

##### *Executive Order 13175—Consultation and Coordination With Indian Tribal Governments*

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve Federal regulations involving Indian lands.

##### *Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy*

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) Considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 et seq.).

Regulatory Flexibility Act

The Department of the Interior certifies that a portion of the provisions in this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because they are based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations. The Department of the Interior also certifies that the provisions in this rule that are not based upon counterpart Federal regulations will not have a significant economic impact on a substantial number of small entities under the

Regulatory Flexibility Act (5 U.S.C. 601 et seq.). This determination is based on the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that a portion of the State provisions are based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule. For the portion of the State provisions that is not based upon counterpart Federal regulations, this determination is based upon the fact that the State provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or

tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that a portion of the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate. For the portion of the State provisions that is not based upon counterpart Federal regulations, this determination is based upon the fact that the State provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

List of Subjects in 30 CFR Part 946

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 29, 2007.

Brent Wahlquist, Regional Director, Appalachian Region.

For the reasons set out in the preamble, 30 CFR Part 946 is amended as set forth below:

PART 946—VIRGINIA

1. The authority citation for part 946 continues to read as follows:

Authority: 30 U.S.C. 1201 et seq.

2. Section 946.15 is amended in the table by adding a new entry in chronological order by "Date of final publication" to read as follows:

§ 946.15 Approval of Virginia regulatory program amendments.

\* \* \* \* \*

Original amendment submission date	Date of final publication	Citation/description
* February 13, 2007 .....	* July 5, 2007 .....	* 4 VAC 25-130-785.25(c)(deleted); 4 VAC 25-130-816.116 and 817.116(c)(2)(ii).

[FR Doc. E7-12979 Filed 7-3-07; 8:45 am] BILLING CODE 4310-05-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard 33 CFR Part 100

[CGD09-07-052]

RIN 1625-AA08

Special Local Regulations for Marine Events; Port Huron to Mackinac Island Race

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce Special Local Regulations for the Port Huron to Mackinac Island Race. This action is necessary to safely control vessel movements in the vicinity of the race and provide for the safety of the general boating public and commercial shipping. During this period, no person or vessel may enter the regulated area without the permission of the Coast Guard Patrol Commander.