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:


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”.


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:


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 add a new entry for “051079” to read as follows:

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

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDL Laboratories, Inc.</td>
<td>051079</td>
</tr>
<tr>
<td>12720 Dairy Ashford, Sugar Land, TX 77478</td>
<td></td>
</tr>
</tbody>
</table>

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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


§524.2620 [Amended]

4. In paragraph (a)(2) of §524.2620, remove “062749” and add in its place “051079”.


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 remining 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.
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 remining 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 SMSCRA provision quoted above (the entire last sentence was deleted) is twofold: (1) It makes permanent the authority at subsection 510(e) of SMSCRA to approve a permit application for surface coal mining operations on lands eligible for remining 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 remining at subsection 515(b)(20)(B) of SMSCRA.

In its amendment, Virginia is deleting the termination date of September 30, 2004, from three of its program regulations concerning remining. 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 remining. 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 remining must comply with this section.

(b) Any application for a permit under this section shall be made according to all requirements of this chapter 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 SMSCRA.

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 SMSCRA 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 applicable success standard during the growing season of the last 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 remining 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)(ii) 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) Concurrency 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.). 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
graphic 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 that is not based
upon counterpart Federal
regulations, this determination is based upon the
fact that the 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.

Brent Wahlquist,
Regional Director, Appalachian Region.

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.

<table>
<thead>
<tr>
<th>Original amendment</th>
<th>Date of final publication</th>
<th>Citation/description</th>
</tr>
</thead>
</table>

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
Hurton 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.

BILLING CODE 4310–05–P