

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 in 21 CFR Part 510

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

■ 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 part 510 is 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 "Minrad, Inc." and alphabetically add a new entry for "Piramal Critical Care, Inc."; and in the table in paragraph (c)(2), revise the entry for "060307" to read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

| Firm name and address                                                        | Drug labeler code |
|------------------------------------------------------------------------------|-------------------|
| * * *                                                                        | * * *             |
| Piramal Critical Care, Inc.,<br>3950 Schelden Circle,<br>Bethlehem, PA 18017 | 060307            |
| * * *                                                                        | * * *             |

(2) \* \* \*

| Drug labeler code | Firm name and address                                                        |
|-------------------|------------------------------------------------------------------------------|
| * * *             | * * *                                                                        |
| 060307            | Piramal Critical Care, Inc.,<br>3950 Schelden Circle,<br>Bethlehem, PA 18017 |
| * * *             | * * *                                                                        |

Dated: April 15, 2010.

**Elizabeth Rettie,**

*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 2010–9045 Filed 4–19–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 510

[Docket No. FDA–2010–N–0002]

#### New Animal Drugs; Change of Sponsor's Name and Address

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Parnell Laboratories (Aust) Pty. Ltd. to Parnell Technologies Pty. Ltd. In addition, the sponsor's mailing address will be changed.

**DATES:** This rule is effective April 20, 2010.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: [david.newkirk@fda.hhs.gov](mailto:david.newkirk@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Parnell Laboratories (Aust) Pty. Ltd., Century Estate, unit 6, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia, has informed FDA that it has changed its name and address to Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect this change.

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 in 21 CFR Part 510

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

■ 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 part 510 is 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), revise the entry for "Parnell Laboratories (Aust) Pty. Ltd."; and in the table in paragraph (c)(2), revise the entry for "068504" to read as follows:

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

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

| Firm name and address                                                                                  | Drug labeler code |
|--------------------------------------------------------------------------------------------------------|-------------------|
| * * *                                                                                                  | * * *             |
| Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia | 068504            |
| * * *                                                                                                  | * * *             |

(2) \* \* \*

| Drug labeler code | Firm name and address                                                                                  |
|-------------------|--------------------------------------------------------------------------------------------------------|
| * * *             | * * *                                                                                                  |
| 068504            | Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia |
| * * *             | * * *                                                                                                  |

Dated: April 15, 2010.

**Elizabeth Rettie,**

*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 2010–9057 Filed 4–19–10; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG–2009–0370]

RIN 1625–AA11

#### Regulated Navigation Areas; Port of Portland Terminal 4, Willamette River, Portland, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing two Regulated Navigation Areas (RNA) at the Port of Portland Terminal 4 on the Willamette River in

Portland, Oregon. The RNAs are necessary to preserve the integrity of engineered sediment caps placed within Slip 3 and Wheeler Bay at the Portland Harbor Superfund Site as part of a removal action at that site. The RNAs will do so by prohibiting activities that could disturb or damage the engineered sediment caps in that area.

**DATES:** This rule is effective May 20, 2010.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0370 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0370 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail MST1 Jaime Sayers, Waterways Management, USCG Sector Portland; telephone 503-240-9319, e-mail [Jaime.A.Sayers@uscg.mil](mailto:Jaime.A.Sayers@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Regulatory Information**

On December 30, 2009, we published a notice of proposed rulemaking (NPRM) entitled "Regulated Navigation Areas; Port of Portland Terminal 4, Willamette River, Portland, OR" in the *Federal Register* (74 FR 69047). We received one comment on the proposed rule. There were no requests for a public meeting and none was held.

##### **Background and Purpose**

As part of a removal action at the Portland Harbor Superfund Site in 2008, engineered sediment caps were placed within Slip 3 and Wheeler Bay at the Port of Portland Terminal 4 Facility in order to contain underlying contaminated sediment and shoreline soil. The Port of Portland Terminal 4 Facility is located between River Miles 4.1 and 4.5 on the Willamette River.

The engineered sediment caps are designed to be compatible with normal marine operations, but could be damaged by other maritime activities including anchoring, dragging, dredging, or trawling. Such damage

could disrupt the function or affect the integrity of the caps to contain the underlying contaminated sediment and shoreline soil in these areas. As such, the RNAs are necessary to help ensure the engineered sediment caps are protected and will do so by prohibiting certain maritime activities that could disturb or damage them.

##### **Discussion of Comments and Changes**

The one comment received questioned the use, in the Background and Purpose section of the NPRM, of the term "port" rather than "marine" to describe the activities that may take place in the area where the sediment caps are located. In light of the potential confusion about what activities are being discussed, the term "port" was replaced with "marine" in the "Background and Purpose" section of this final rule.

##### **Regulatory Analyses**

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

##### **Regulatory Planning and Review**

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. The Coast Guard has made this determination based on the fact that the RNAs cover a relatively small area and that area can still be used for most maritime activities.

##### **Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. This rule could affect the following entities, some of which might be small entities: the owners or operators of vessels operating in the areas covered by the RNAs. The RNAs would not have a

significant economic impact on a substantial number of small entities, however, because the RNAs cover a relatively small area and that area can still be used for most maritime activities.

##### **Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

##### **Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

##### **Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

##### **Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect 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.

### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are

technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

### Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a regulated navigation area. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, and Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.1326 to read as follows:

#### § 165.1326 Regulated Navigation Areas; Port of Portland Terminal 4, Willamette River, Portland, OR

(a) *Regulated navigation areas.* Each of the following areas is a regulated navigation area:

(1) All waters of the Willamette River in the head of the Port of Portland's Terminal 4 Slip 3, encompassed by a line commencing at 45° 36' 01.861" N/122° 46' 20.995" W thence to 45° 36' 01.455" N/122° 46' 20.887" W thence to 45° 36' 00.993" N/122° 46' 20.714" W

thence to 45° 36' 00.725" N/122° 46' 20.923" W thence to 45° 36' 00.731" N/122° 46' 21.262" W thence to 45° 36' 00.712" N/122° 46' 21.823" W thence to 45° 36' 01.230" N/122° 46' 22.048" W thence to 45° 36' 01.651" N/122° 46' 22.168" W thence to 45° 36' 01.684" N/122° 46' 22.372" W thence to 45° 36' 01.873" N/122° 46' 22.303" W thence to 45° 36' 02.065" N/122° 46' 21.799" W thence to 45° 36' 01.989" N/122° 46' 21.574" W thence to 45° 36' 01.675" N/122° 46' 21.483" W thence to 45° 36' 01.795" N/122° 46' 21.442" W thence to 45° 36' 01.861" N/122° 46' 20.995" W.

(2) All waters of the Willamette River in Wheeler Bay between Slip 1 and Slip 3 in the Port of Portland's Terminal 4, encompassed by a line commencing at 45° 36' 10.634" N/122° 46' 39.056" W thence to 45° 36' 10.269" N/122° 46' 37.140" W thence to 45° 36' 10.027" N/122° 46' 36.050" W thence to 45° 36' 09.722" N/122° 46' 34.181" W thence to 45° 36' 09.425" N/122° 46' 33.118" W thence to 45° 36' 08.960" N/122° 46' 32.150" W thence to 45° 36' 08.653" N/122° 46' 31.681" W thence to 45° 36' 08.191" N/122° 46' 31.341" W thence to 45° 36' 07.886" N/122° 46' 31.269" W thence to 45° 36' 07.517" N/122° 46' 31.038" W thence to 45° 36' 07.235" N/122° 46' 31.066" W thence to 45° 36' 07.040" N/122° 46' 30.941" W thence to 45° 36' 06.697" N/122° 46' 30.987" W thence to 45° 36' 06.509" N/122° 46' 31.251" W thence to 45° 36' 06.201" N/122° 46' 31.517" W thence to 45° 36' 06.081" N/122° 46' 1.812" W thence to 45° 36' 06.550" N/122° 46' 32.124" W thence to 45° 36' 06.970" N/122° 46' 31.895" W thence to 45° 36' 07.172" N/122° 46' 31.868" W thence to 45° 36' 07.883" N/122° 46' 32.316" W thence to 45° 36' 08.370" N/122° 46' 32.927" W thence to 45° 36' 08.775" N/122° 46' 33.888" W thence to 45° 36' 09.121" N/122° 46' 35.337" W thence to 45° 36' 09.230" N/122° 46' 36.166" W thence to 45° 36' 09.442" N/122° 46' 37.759" W thence to 45° 36' 09.865" N/122° 46' 39.511" W thence to 45° 36' 10.421" N/122° 46' 39.469" W thence to 45° 36' 10.634" N/122° 46' 39.056" W.

(b) *Regulations.* All vessels are prohibited from anchoring, dragging, dredging, or trawling in the regulated navigation areas established in paragraph (a) of this section.

Dated: April 2, 2010.

**G.T. Blore,**

*Rear Admiral, U.S. Coast Guard*

*Commander, Thirteenth Coast Guard District.*

[FR Doc. 2010-9018 Filed 4-19-10; 8:45 am]

**BILLING CODE 9110-04-P**