

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 558**

[Docket No. FDA-2013-N-0002]

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

**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 and address from Purina Mills, Inc., to Purina Nutrition LLC, and a change of sponsor for a new animal drug application (NADA) from Land O'Lakes Purina Feed LLC to Purina Nutrition LLC. The regulations are also being amended to reflect that Zoetis Inc. is a sponsor of approved NADAs.

**DATES:** This rule is effective May 13, 2013.

**FOR FURTHER INFORMATION CONTACT:** Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240-276-8300, email: [steven.vaughn@fda.hhs.gov](mailto:steven.vaughn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812, has informed FDA that it has changed its name and address to Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910. Land O'Lakes Purina Feed LLC, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 118-509 for Pasture Gainer Block 37 R350 and Pasture Gainer Block 20 R350 to Purina Nutrition LLC. Accordingly, the Agency is amending the regulations in 21 CFR parts 510 and 558 to reflect the change of name and address and the transfer of ownership.

In addition, Zoetis Inc. is a sponsor of approved NADAs. At this time, FDA is amending 21 CFR 510.600 to add entries for this firm.

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 558

Animal drugs, Animal feeds.

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 558 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 "Land O'Lakes Purina Feed LLC" and "Purina Mills, Inc.," and alphabetically add entries for "Purina Nutrition LLC" and "Zoetis Inc.;" and in the table in paragraph (c)(2), remove the entry for "066071", revise the entry for "017800", and numerically add an entry for "054771" 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
Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910 ...	017800
Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 .....	054771

(2) \* \* \*

Drug labeler code	Firm name and address
017800 ...	Purina Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126-2910.
054771 ...	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

**§ 558.355 [Amended]**

■ 4. In § 558.355, paragraph (f)(7)(iii)(a), remove "066071" and add in its place "017800".

Dated: May 8, 2013.

**Bernadette Dunham,**

Director, Center for Veterinary Medicine.

[FR Doc. 2013-11283 Filed 5-10-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

[K00103 12/13 A3A10; 134D0102DR-DS5A300000-DR.5A311.IA000113]

**25 CFR Part 162**

RIN 1076-AE73

**Residential, Business, and Wind and Solar Resource Leases on Indian Land**

**AGENCY:** Bureau of Indian Affairs, Interior.

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

**SUMMARY:** The Bureau of Indian Affairs (BIA) published a rule in the **Federal Register** of December 5, 2012, announcing the revisions to regulations addressing non-agricultural surface leasing of Indian land. This notice makes a minor correction to redesignate section numbers for sections that were moved to a new subpart.

**DATES:** This correction is effective on May 13, 2013.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Appel, Acting Director, Office of Regulatory Affairs & Collaborative Action, (202) 273-4680; [elizabeth.appel@bia.gov](mailto:elizabeth.appel@bia.gov).

**SUPPLEMENTARY INFORMATION:**

**Need for Correction**

The final regulations (77 FR 72440) addressing non-agricultural surface leasing of Indian land, and redesignating certain sections related to agricultural leases, failed to specifically redesignate the section numbers of sections being moved to subpart F. This document corrects that error.

**List of Subjects in 25 CFR Part 162**

Indians—lands.

Accordingly, 25 CFR part 162 is corrected by making the following correcting amendment:

**PART 162—LEASES and PERMITS**

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

**Authority:** 5 U.S.C. 301, R.S. 463 and 465; 25 U.S.C. 2 and 9. Interpret or apply sec. 3, 26 Stat. 795, sec. 1, 28 Stat. 305, secs. 1, 2, 31 Stat. 229, 246, secs. 7, 12, 34 Stat. 545, 34 Stat. 1015, 1034, 35 Stat. 70, 95, 97, sec. 4, 36 Stat. 856, sec. 1, 39 Stat. 128, 41 Stat. 415, as amended, 751, 1232, sec. 17, 43 Stat. 636, 641, 44 Stat. 658, as amended, 894, 1365, as amended, 47 Stat. 1417, sec. 17, 48 Stat. 984, 988, 49 Stat. 115, 1135, sec. 55, 49 Stat. 781, sec. 3, 49 Stat. 1967, 54 Stat. 745, 1057, 60 Stat. 308, secs. 1, 2, 60 Stat. 962, sec. 5, 64 Stat. 46, secs. 1, 2, 4, 5, 6, 64 Stat. 470, 69 Stat. 539, 540, 72 Stat. 968, 107 Stat. 2011, 108 Stat. 4572, March 20, 1996, 110 Stat. 4016; 25 U.S.C. 380, 393, 393a, 394, 395, 397, 402, 402a, 403, 403a, 403b, 403c, 409a, 413, 415, 415a, 415b, 415c, 415d, 416, 477, 635, 2201 et seq., 3701, 3702, 3703, 3712, 3713, 3714, 3715, 3731, 3733, 4211; 44 U.S.C. 3101 et seq.

■ 2. Under the heading Subpart F—Special Requirements for Certain Reservations, redesignate §§ 162.500 through 162.503, as §§ 162.600 through 162.603.

Dated: May 3, 2013.

**Kevin K. Washburn,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2013–11241 Filed 5–10–13; 8:45 am]

**BILLING CODE 4310–6W–P**

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 799**

[EPA–HQ–OPPT–2005–0033; FRL–9369–1]

RIN 2070–AD16

**Revocation of TSCA Section 4 Testing Requirements for One High Production Volume Chemical Substance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This final rule implements EPA's decision to revoke certain testing requirements promulgated under the Toxic Substance Control Act (TSCA) for the High Production Volume (HPV) chemical substance, benzenesulfonic acid, [[4-[[4-(phenylamino)phenyl][4-(phenylimino)-2,5-cyclohexadien-1-ylidene]methyl]phenyl]amino]- (CAS No. 1324–76–1), also known as C.I. Pigment Blue 61. After publication in the **Federal Register** of a final rule requiring testing for C.I. Pigment Blue 61, EPA received adequate, existing studies which eliminated the need for testing.

**DATES:** This final rule is effective June 12, 2013.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2005–0033, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 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 OPPT Docket is (202) 566–0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:**

*For technical information contact:* Yvonne Gonzalez, Chemical Control Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (202) 564–2912; email address: [gonzalez.yvonne@epa.gov](mailto:gonzalez.yvonne@epa.gov).

*For general information contact:* The TSCA–Hotline, ABVI–Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. Does this action apply to me?**

This action is directed to the public in general and may be of particular interest to those persons who manufacture (defined by statute to include import), process, or export the chemical substance identified in this document. Because other persons may also be interested, the Agency has not attempted to describe all the specific persons that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

**II. Background***A. What action is the Agency taking?*

In this document, EPA is amending the TSCA section 4(a) chemical testing requirements for one HPV chemical substance included in 40 CFR 799.5085. Specifically, the amendment revokes some of the testing requirements for C.I. Pigment Blue 61. EPA bases its decision on information (discussed in Unit III.) received since publication of the final rule (Ref. 1) that established testing

requirements for this chemical substance.

In the **Federal Register** issue of March 16, 2012 (Ref. 2), EPA issued a direct final rule revoking some or all of the testing requirements for 10 chemical substances, including C.I. Pigment Blue 61. EPA received an adverse comment pertaining to a statement in the preamble of the direct final rule that certain full studies for C.I. Pigment Blue 61 had been claimed as Confidential Business Information (CBI) and were, therefore, not available to the public, although robust summaries were available in the docket. The Environmental Defense Fund (EDF) objected to EPA's placing the robust summaries in the docket rather than applying the disclosure requirements of TSCA section 14(b) to the full health and safety studies. Consequently, in accordance with the procedures described in the March 16, 2012 **Federal Register** document (Ref. 2), EPA withdrew the revocation of certain testing requirements for C.I. Pigment Blue 61 in a separate final rule document published in the **Federal Register** issue of May 14, 2012 (Ref. 3), and also published a proposed rule document in the same **Federal Register** issue (Ref. 4) asking for comment. EPA is now issuing the final rule based on the May 14, 2012 **Federal Register** proposed rule document (Ref. 4).

*B. What is the Agency's authority for taking this action?*

Section 4(a) of TSCA authorizes EPA to require testing if certain findings are made. The TSCA section 4(a) findings include:

1. The chemical substance was produced in substantial quantities.
2. There are insufficient data upon which the effects of manufacture, distribution, processing, use, or disposal of a chemical substance on health or the environment can reasonably be determined or predicted.
3. Testing of the chemical substance with respect to such effects is necessary to develop such data. (See TSCA section 4(a)(1)(B)(i), (ii), and (iii); see also Ref. 1).

EPA amends the testing requirements for C.I. Pigment Blue 61 because some of the findings that EPA made under the criteria listed in this unit for this chemical substance are no longer supported.

**III. Amendment to Chemical Testing Requirements**

On July 17, 2006, the Color Pigments Manufacturers Association (CPMA) submitted a test plan for C.I. Pigment Blue 61. CPMA also submitted robust