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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier A. Corbin

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.

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**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 [*insert date of publication in the Federal Register*].

**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.

cv0749

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*NFL1*

## 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.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

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

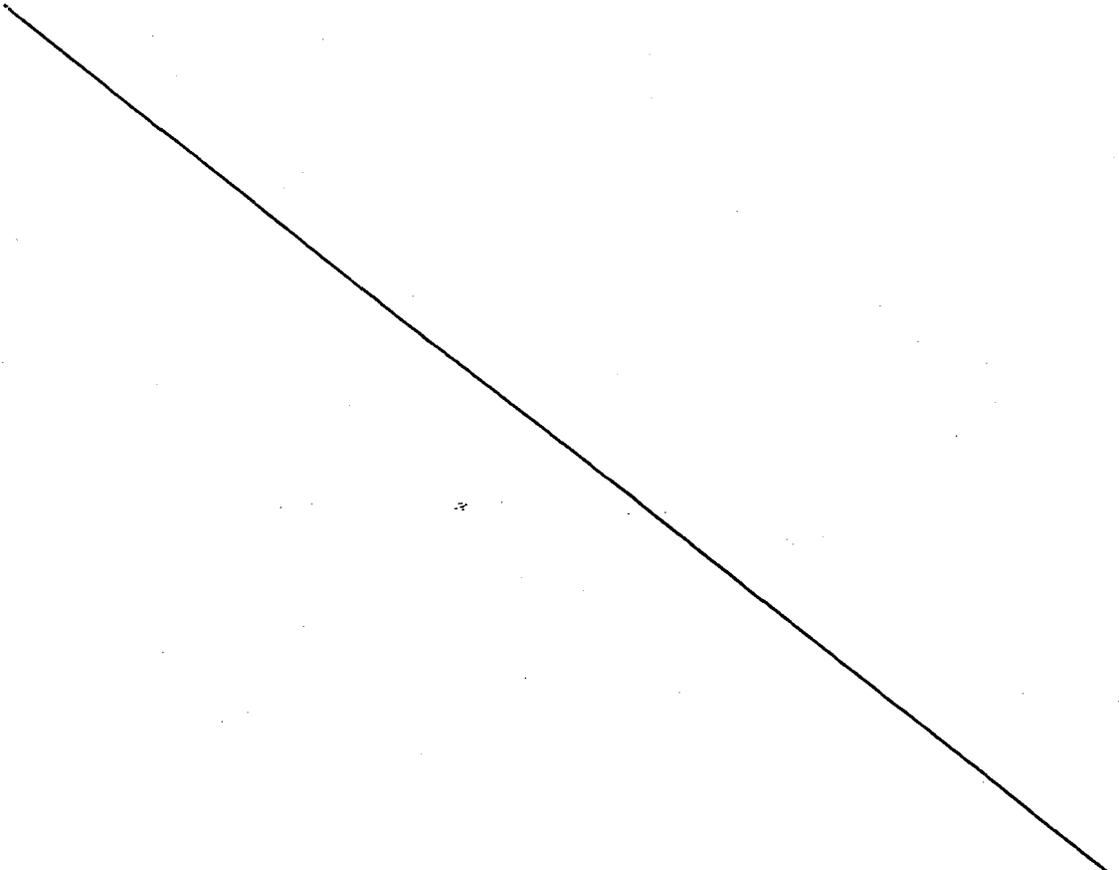
(2) \* \* \*

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.

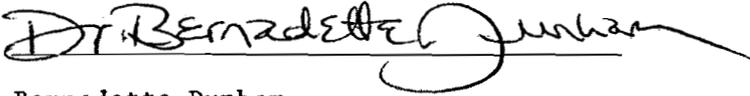


§ 524.2620 [Amended]

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

Dated: 6/21/2007

June 21, 2007.



Bernadette Dunham,  
Deputy Director,  
Center for Veterinary Medicine.

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