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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Display Date 2-3-03

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Certifier A. Corbin

**Certain Other Dosage Form New Animal Drugs; Formalin Solution**

**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 approval of a supplemental new animal drug application (NADA) filed by Natchez Animal Supply Co. The supplemental NADA provides for use of formalin in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs. Minor corrections to the regulations are also being made.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-131), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: jgotthar@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Natchez Animal Supply Co., 201 John R. Junkin Dr., Natchez, MS 39120, filed a supplement to NADA 137-687 that provides for use of formalin in a water bath for the control of certain external parasites on finfish and shrimp and for the control of certain fungi on finfish eggs. The supplemental NADA is approved as of November 25, 2002, and the regulations are amended in 21 CFR 529.1030 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

cv0213

**NADA. 137-687**

**NFR-1**

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 529**

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 part 529 is amended as follows:

### **PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 529 continues to read as follows:

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

#### **§ 529.1030 [Amended]**

2. Section 529.1030 *Formalin solution* is amended as follows:

(a) In the section heading and in paragraph (a) by removing the word “solution” following the word “Formalin”;

(b) By revising the introductory text of paragraph (b);

(c) In paragraph (b)(1) by removing “No. 050378” and by adding in its place “Nos. 049968 and 050378”;

(d) In paragraph (b)(2) by removing “Nos. 049968 and” and by adding in its place “No.”;

(e) In paragraph (d)(2)(i), in the table, in the heading to the second column, by adding “daily” after “1 hour”; and

(f) In paragraph (d)(2)(iv), in the first column in the table by removing “½F” each time it occurs and by adding in its place “°F”.

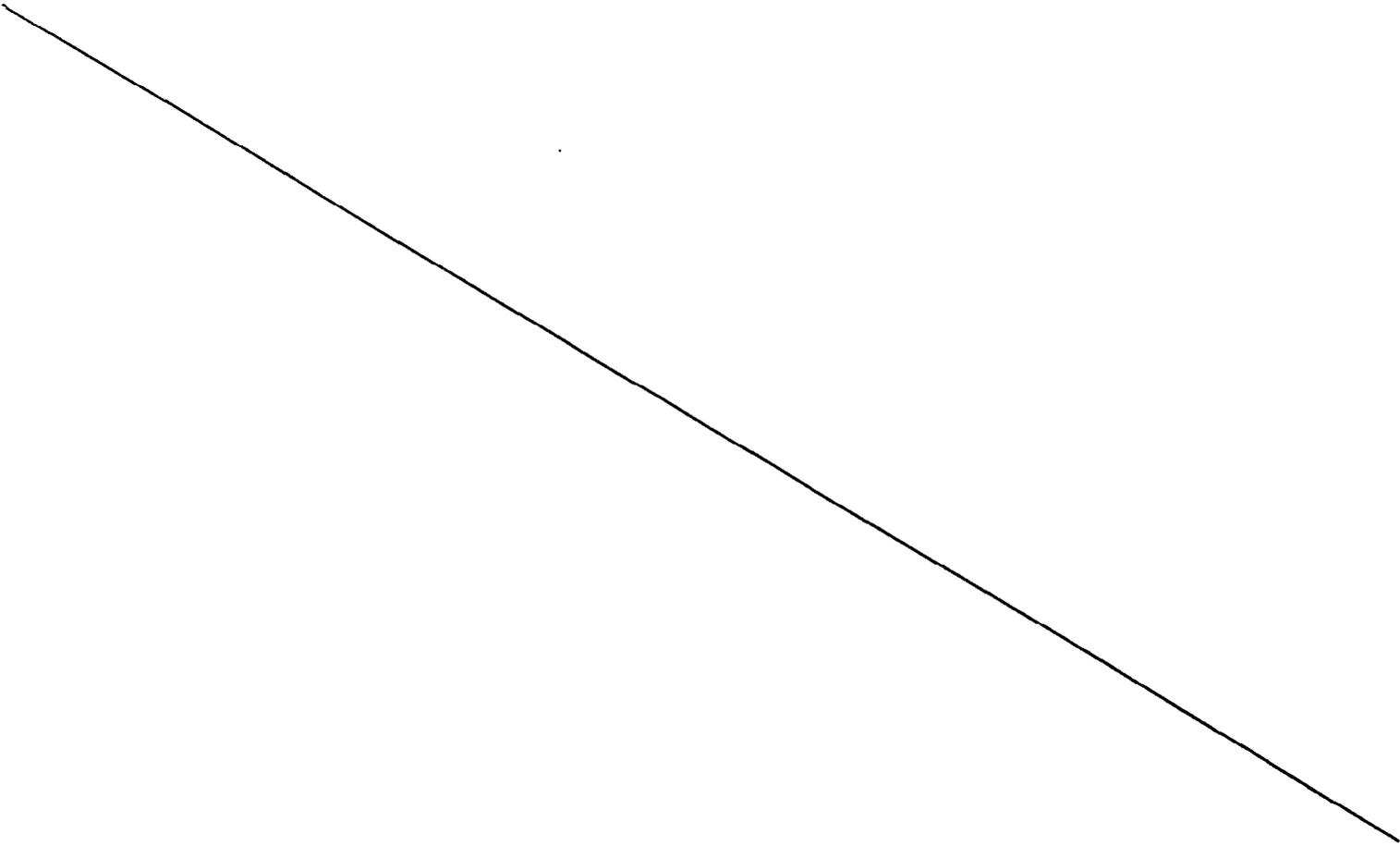
The revision is to read as follows:

**§ 529.1030      Formalin.**

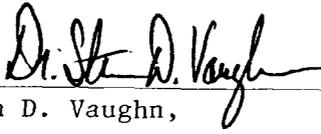
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(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

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Dated: January 21, 2003  
January 21, 2003.



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