

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 5****Delegations of Authority and Organization; Center for Devices and Radiological Health**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to functions performed by the Center for Devices and Radiological Health (CDRH). This amendment updates the titles of CDRH delegates and organizational components to reflect the organizational restructuring and also publishes delegations of authority to additional positions within CDRH. This action is intended to ensure the accuracy and consistency of the regulations.

**EFFECTIVE DATE:** December 24, 1997.

**FOR FURTHER INFORMATION CONTACT:**

Debra A. Baclawski, Center for Devices and Radiological Health (HFZ-026), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-443-1060, or

Donna G. Page, Division of Management Systems and Policy (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

**SUPPLEMENTARY INFORMATION:** CDRH has undergone an organizational restructuring (58 FR 35959, July 2, 1993), which was approved by the Commissioner of Food and Drugs. The authorities delegated to the CDRH officials are amended in this document to reflect new titles and organization placement under the restructuring and also it publishes delegations of authority to additional positions within the center.

The most significant changes are: (1) The establishment of a second Deputy Director in the Office of the Director, CDRH, and in the Office of Device Evaluation; (2) the reorganization and retitling of the Office of Compliance and Surveillance to the Office of Compliance; and (3) the redelegation of authority to each of the Division Directors in the Office of Compliance.

Further redelegation of the authorities delegated is not authorized at this time. Authority delegated to a position may be exercised by a person officially

designated to serve in such position in an acting capacity or on a temporary basis.

**List of Subjects in 21 CFR Part 5**

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

**PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION**

1. The authority citation for 21 CFR part 5 continues to read as follows:

**Authority:** 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261-1282, 3701-3711a; 15 U.S.C. 1451-1461; 21 U.S.C. 41-50, 61-63, 141-149, 321-394, 467f, 679(b), 801-886, 1031-1309; 35 U.S.C. 156; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u-300u-5, 300aa-1; 1395y, 3246b, 4332, 4831(a), 10007-10008; E.O. 11921, 41 FR 24294, 3 CFR, 1977 Comp., p. 124-131; E.O. 12591, 52 FR 13414, 3 CFR, 1988 Comp., p. 220-223

2. Section 5.22 is amended by revising paragraphs (a)(10)(i), (a)(10)(ii), (a)(10)(iv), and (a)(10)(v) to read as follows:

**§ 5.22 Certification of true copies and use of Department seal.**

(a) \* \* \*

(10)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Associate Director and Deputy Associate Director for Management and Systems, CDRH.

\* \* \* \* \*

(iv) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

(v) Freedom of Information Officers, CDRH.

\* \* \* \* \*

3. Section 5.23 is amended by revising paragraphs (c)(1) through (c)(4) to read as follows:

**§ 5.23 Disclosure of official records.**

\* \* \* \* \*

(c) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy, Division of Program Operations, Office of Compliance, CDRH.

(4) The Chief, Information Processing and Automation Branch, Division of

Program Operations, Office of Compliance, CDRH.

\* \* \* \* \*

4. Section 5.25 is amended by revising paragraphs (a)(2) and (b) to read as follows:

**§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.**

(a) \* \* \*

(2) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

\* \* \* \* \*

(b) The Director and Deputy Directors, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 356 of the act.

\* \* \* \* \*

5. Section 5.26 is amended by revising paragraph (c) to read as follows:

**§ 5.26 Service fellowships.**

\* \* \* \* \*

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director, Office of Systems and Management, CDRH.

\* \* \* \* \*

6. Section 5.28 is revised to read as follows:

**§ 5.28 Cardiac pacemaker devices and pacemaker leads.**

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)), as amended.

7. Section 5.30 is amended by revising paragraphs (b) and (c)(4) to read as follows:

**§ 5.30 Hearings.**

\* \* \* \* \*

(b) The Director and Deputy Directors, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) \* \* \*

(4) The Director and Deputy Directors, CDRH.

\* \* \* \* \*

8. Section 5.31 is amended by revising paragraphs (c)(3) and (e)(5) to read as follows:

**§ 5.31 Petitions under part 10.**

\* \* \* \*

(c) \* \* \*

(3) The Director and Deputy Directors, Center for Devices and Radiological Health.

\* \* \* \*

(e) \* \* \*

(5) The Director and Deputy Directors, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

\* \* \* \*

9. Section 5.33 is amended by revising paragraph (b) to read as follows:

**§ 5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.**

\* \* \* \*

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director, Office of Device Evaluation, CDRH.

\* \* \* \*

10. Section 5.37 is amended by revising paragraphs (a)(2)(i) through (a)(2)(iii) and (b)(1) through (b)(3), and by removing paragraph (a)(2)(iv) and removing and reserving (b)(4) to read as follows:

**§ 5.37 Issuance of reports of minor violations.**

(a) \* \* \*

(2)(i) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

\* \* \* \*

(b) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) For medical devices assigned to their respective divisions, the Division Directors, Office of Compliance, CDRH.

\* \* \* \*

11. Section 5.45 is amended by revising paragraphs (b) introductory text, (c)(1) and (c)(2), and (e)(1)(i) through (e)(1)(iii) to read as follows:

**§ 5.45 Imports and exports.**

\* \* \* \*

(b) The Director and Deputy Directors, Center for Devices and Radiological

Health (CDRH); the Director and Deputy Director, Office of Compliance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 360 of the Public Health Service Act (PHSA), to perform the following functions or to designate officials to:

\* \* \* \*

(c) \* \* \*

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \*

(e) \* \* \*

(1) \* \* \*

(i) The Director and Deputy Directors, CDRH.

(ii) The Director and Deputy Director, Office of Compliance, CDRH.

(iii) The Director and Deputy Director, Division of Program Operations, Office of Compliance, CDRH.

\* \* \* \*

12. Section 5.46 is revised to read as follows:

**§ 5.46 Manufacturer's resident import agents.**

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter.

13. Section 5.47 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

**§ 5.47 Detention of adulterated or misbranded medical devices.**

\* \* \* \*

(a) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \*

14. Section 5.49 is amended by revising paragraph (a) to read as follows:

**§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.**

\* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \*

15. Section 5.50 is amended by revising paragraph (a) to read as follows:

**§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.**

\* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

\* \* \* \*

16. Section 5.51 is amended by revising paragraphs (a)(1) and (b)(1) to read as follows:

**§ 5.51 Determination of classification of devices.**

(a) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \*

(b) \* \* \*

(1) The Director and Deputy Directors, CDRH, and the Director, Deputy Directors, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

\* \* \* \*

17. Section 5.52 is amended by revising paragraph (a) to read as follows:

**§ 5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.**

\* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \*

18. Section 5.53 is amended by revising paragraphs (a)(1), (b)(1)(i), and (c) to read as follows:

**§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.**

(a) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \*

(b)(1) \* \* \*

(i) The Director and Deputy Directors, CDRH, and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \*

(c) The Director and Deputy Directors, CDRH, for medical devices assigned to

their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515(d), (e), and (g) and 520(h)(1) of the act.

19. Section 5.54 is amended by revising paragraph (a) to read as follows:

**§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

20. Section 5.55 is amended by revising paragraph (a) to read as follows:

**§ 5.55 Orders to repair or replace, or make refunds for, medical devices.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

21. Section 5.56 is amended by revising paragraphs (a) and (b) to read as follows:

**§ 5.56 Recall authority.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

22. Section 5.57 is amended by revising paragraphs (a) through (c) to read as follows:

**§ 5.57 Temporary suspension of a medical device application.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

(c) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

\* \* \* \* \*

23. Section 5.59 is amended by revising paragraph (a)(1) to read as follows:

**§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.**

(a) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

24. Section 5.60 is amended by revising paragraphs (a)(1) through (a)(4), (a)(6), and (b)(1) through (b)(5) to read as follows:

**§ 5.60 Required and discretionary postmarket surveillance.**

(a) \* \* \*

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Division Directors and Associate Division Directors, Office of Device Evaluation, CDRH.

\* \* \* \* \*

(6) The Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

(b) \* \* \*

(1) The Director and Deputy Directors, CDRH.

(2) The Director and Deputy Director, Office of Surveillance and Biometrics, CDRH.

(3) The Director and Deputy Director, Division of Postmarket Surveillance, Office of Surveillance and Biometrics, CDRH.

(4) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Compliance, CDRH.

\* \* \* \* \*

25. Section 5.78 is amended by revising paragraph (b) to read as follows:

**§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.**

\* \* \* \* \*

(b) The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

26. Section 5.86 is amended by revising paragraphs (a) and (b), and by removing paragraph (c) to read as follows:

**§ 5.86 Variances from performance standards for electronic products.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

27. Section 5.87 is amended by revising paragraphs (a) and (b), and by removing paragraph (c) to read as follows:

**§ 5.87 Exemption of electronic products from performance standards and prohibited acts.**

\* \* \* \* \*

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance, CDRH.

28. Section 5.88 is revised to read as follows:

**§ 5.88 Testing programs and methods of certification and identification for electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health, (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act (the act), and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the act.

29. Section 5.89 is amended by revising paragraphs (a) introductory text and (b) introductory text to read as follows:

**§ 5.89 Notification of defects in, and repair or replacement of, electronic products.**

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs, relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

\* \* \* \* \*

(b) The Director and Deputy Director, Office of Compliance, CDRH, and the

Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

\* \* \* \* \*

30. Section 5.90 is revised to read as follows:

**§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

31. Section 5.91 is revised to read as follows:

**§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.**

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

32. Section 5.92 is revised to read as follows:

**§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.**

The Director and Deputy Directors, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

Dated: December 16, 1997.

**William K. Hubbard,**

Associate Commissioner for Policy Coordination.

[FR Doc. 97-33482 Filed 12-23-97; 8:45 am]

BILLING CODE 4160-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Decoquinatate and Bacitracin Zinc With Roxarsone**

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by ALPHARMA INC. The ANADA provides for using approved decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency.

**EFFECTIVE DATE:** December 24, 1997.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1602.

**SUPPLEMENTARY INFORMATION:**

ALPHARMA INC., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA 200-206 that provides for combining approved decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds for broilers containing decoquinatate 27.2 grams per ton (g/t) and bacitracin zinc 12 to 50 g/t with roxarsone 11 to 45 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. mivati*, *E. maxima*, and *E. brunetti*, and for increased rate of weight gain and improved feed efficiency.

ALPHARMA INC.'s, ANADA 200-206 is approved as a generic copy of Rhone Poulenc Inc.'s NADA 91-326. The ANADA is approved as of December 24, 1997 and the regulations are amended in 21 CFR 558.195(d) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of three single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make a Type C medicated feed from a

Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of decoquinatate, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds as provided in NADA 200-206 is limited to manufacture in a licensed feed mill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33 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.

**List of Subjects in 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 part 558 is amended as follows:

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

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

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

**§ 558.195 [Amended]**

2. Section 558.195 *Decoquinatate* is amended in the table in paragraph (d) in the entry for "27.2 (0.003 pct), Roxarsone 11 to 45 (0.0012-0.005 pct.) plus Bacitracin 12 to 50" under "Limitations" by removing "No. 011716" and adding in its place "Nos. 011716 and 046573".

Dated: October 30, 1997.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

[FR Doc. 97-33638 Filed 12-23-97; 8:45 am]

BILLING CODE 4160-01-F