§ 814.42 Filing a PMA.

* * * * *

(e) * * *

(5) The PMA is not accompanied by a statement of either certification or disclosure as required by part 54 of this chapter.

29. Section 814.112 is amended by adding new paragraph (a)(4) to read as follows:

§ 814.112 Filing an HDE.

(a) * * *

(4) The HDE is not accompanied by a statement of either certification or disclosure, or both, as required by part 54 of this chapter.

* * * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

30. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

31. Section 860.123 is amended by adding new paragraph (a)(10) to read as follows:

§ 860.123 Reclassification petition: Content and form.

(a) * * *

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

* * * * *

Dated: October 15, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–2407 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 524, and 558

[Docket No. 97N–0508]

Animal Drugs, Feeds, and Related Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of eight new animal drug applications (NADA's) for which the sponsors have requested withdrawal of approval. The NADA's provide for use of products which are no longer made or marketed. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: February 12, 1998.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1722.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA has withdrawn approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
38–247	Hygromycin B Type A medicated article	Mountaire Feeds, Inc., 124 East Fifth, P.O. Box 5391, North Little Rock, AR 72119, formerly Mountaire Vitamins, Inc., 400 North Poplar St., P.O. Box 9210, North Little Rock, AR 72119
44–013	Tylosin Type A medicated article	do.
65–273	Chloramphenicol capsules, USP	Zenith Goldline Pharmaceuticals, Inc., 140 Legrand Ave., Northvale, NJ 07647, formerly Zenith Laboratories, Inc., 50 Williams Dr., Ramsey, NJ 07446
65–456	Tetracycline HCl capsules, USP	do.
95–736	Hygromycin B Type A medicated article	Mountaire Feeds, Inc.
98–895	Starbar GX–118 Topical (phosmet)(prolate)	Wellmark International, 1000 Tower Lane, Bensenville, IL 60106, formerly Sandoz Agro, Inc., 1300 East Touhy Ave., Des Plaines, IL 60018
137–138	Pyrantel tartrate Type A medicated article	Mountaire Feeds, Inc.
139–239	Banminth (pyrantel tartrate) Type A medicated article	Growmark, Inc., 950 North Meridian St., Indianapolis, IN 46204–3909, formerly at 1701 Towanda Ave., Bloomington, IL 61701

The sponsors requested withdrawal of approval of the NADA's under 21 CFR 514.115(d) because the products are no longer made or marketed.

The regulations are amended in 21 CFR 520.390b(b)(1), 520.2345a(b)(4), 524.1742(b), 558.274(a)(6) and (c)(1)(i), 558.485(a)(21) and (a)(25), and 558.625(b)(84) to remove those portions which reflect approval of these NADA's.

Also, with withdrawal of approval of these NADA's, these firms are no longer sponsors of approved NADA's. Therefore, 21 CFR 510.600(c)(1) and (c)(2) are amended to remove entries for the firms.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520 and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 524, 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.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by

removing the entries for ''Growmark, Inc.,'' ''Mountaire Vitamins, Inc.,'' ''Sandoz Agro, Inc.,'' and ''Zenith Laboratories, Inc.,'' and in the table in paragraph (c)(2) by removing the entries for ''000172'', ''011536'', ''020275'', and ''043734''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.390b [Amended]

4. Section 520.390b *Chloramphenicol capsules* is amended in paragraph (b)(1) by removing ''000172''.

§ 520.2345a [Amended]

5. Section 520.2345a *Tetracycline hydrochloride capsules* is amended by removing paragraph (b)(4).

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1742 [Amended]

7. Section 524.1742 *N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid* is amended in paragraph (b) by removing the phrase ''and 011536''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.274 [Amended]

9. Section 558.274 *Hygromycin B* is amended by removing and reserving paragraph (a)(6) and in the table in paragraph (c)(1)(i), under the ''sponsor'' column, by removing ''043734''.

§ 558.485 [Amended]

10. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraphs (a)(21) and (a)(25).

§ 558.625 [Amended]

11. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(84).

Dated: January 8, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–2410 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 203

RIN 0790–AG14

Technical Assistance for Public Participation (TAPP) in Defense Environmental Restoration Activities

AGENCY: Office of the Deputy Under Secretary of Defense for Environmental Security (DUSD(ES)), DOD.

ACTION: Final rule.

SUMMARY: Pursuant to the National Defense Authorization Act (NDAA) of 1996, the Department of Defense (DoD) is finalizing a rule to provide technical assistance to local community members of Restoration Advisory Boards (RABs) and Technical Review Committee (TRCs). RABs and TRCs are established to review and comment on DoD environmental restoration activities at military installations and formerly used defense sites within the United States and its territories.

EFFECTIVE DATE: This rule is effective February 2, 1998.

FOR FURTHER INFORMATION CONTACT: Patricia Ferrebee or Marcia Read, Office of the Deputy Under Secretary of Defense for Environmental Security, 3400 Defense Pentagon, Washington, D.C., 20301–3400, telephone (703) 697–5372 or (703) 697–7475.

SUPPLEMENTARY INFORMATION: The official record for this rulemaking is kept in a paper format. Accordingly, DoD has transferred all electronic or digital comments received into paper form and placed them into the official record, with all of the comments received in writing.

The Department of Defense's responses to comments have been incorporated in a response to comments document, which has been placed into the official record for this rulemaking. The major comments and responses are discussed in the Response to Comments section of this preamble.

Any person wishing to review the official record, or be provided copies of documents in the official record, for this rulemaking should contact Patricia Ferrebee at Office of the Deputy Under Secretary of Defense for Environmental Security, 3400 Defense Pentagon, Washington, D.C. 20301–3400, in writing, or by telephone at (703) 697–5372.

Preamble Outline

I. Legal Authority
II. Background
III. Summary of Significant Changes from Proposed Rule
IV. Description of the Final Rule and Responses to Major Comments
A. TAPP Process
B. Eligible Applicants
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D. Technical Assistance for Public Participation Provider Qualifications
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I. Legal Authority

This rule is issued under the authority of Section 2705 of Title 10, United States Code. Subsections (c) and (d) of Section 2705 encourage the Department of Defense to establish either a Technical Review Committee (TRC) or Restoration Advisory Board (RAB) to review and comment on DoD actions at military installations undertaking environmental restoration activities. Section 2705(e) permits the Department of Defense to obtain, from private sector sources, technical assistance to help TRCs and RABs better understand the scientific and engineering issues underlying an installation's environmental restoration activities. TRCs and RABs may request this assistance only if:

(1) The TRC or RAB demonstrates that the Federal, State, and local agencies responsible for overseeing environmental restoration at the installation and DoD personnel do not have the technical expertise necessary for achieving the objective for which the technical assistance is to be obtained; or

(2) The technical assistance—

(a) Is likely to contribute to the efficiency, effectiveness, or timeliness of environmental restoration activities at the installation; and

(b) Is likely to contribute to community acceptance of environmental restoration activities at the installation.

Funding for this technical assistance program will come from the Environmental Restoration Accounts established for Army, Navy, and Air Force for operating installations, and from the DoD Component's base closure account for transferring or closing installations. For Defense Agencies the Defense-Wide environmental restoration account will be the source of funds for assistance at operating installations. The Environmental Restoration Account for Formerly Used Defense sites will fund technical assistance at formerly used defense sites.