

stenocephala) in puppies and dogs and to prevent reinfections of *T. canis* in puppies and adult dogs and in lactating bitches after whelping. The product contains pyrantel pamoate equivalent to 4.54 milligrams of pyrantel base.

Approval of ANADA 200-007 for Happy Jack, Inc.'s, pyrantel pamoate suspension is as a generic copy of Pfizer's NADA 100-237 Nemex-2™ (pyrantel pamoate). The ANADA is approved as of October 30, 1996, and the regulations are amended in 21 CFR 520.2043(b)(2) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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, 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 25.24(d)(1)(i) 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 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.2043 is amended by adding a new sentence at the end of paragraph (b)(2) to read as follows:

§ 520.2043 Pyrantel pamoate suspension.

* * * * *

(b) * * *

(2) * * * See No. 023851 for use of 4.54 milligrams per milliliter product.

* * * * *

Dated: November 22, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 96-30653 Filed 11-29-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; 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 the change of sponsor for an approved new animal drug application (NADA) for Biocraft Laboratories, Inc., and A. H. Robins Co.

EFFECTIVE DATE: December 2, 1996.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: A. H. Robins Co., P.O. Box 518, Fort Dodge, IA 50501-0518, and Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, are no longer cosponsors of NADA 140-889. This arrangement was terminated sometime ago, but the agency failed to reflect the change in the regulations. Biocraft Laboratories, Inc., now exclusively owns NADA 140-889 and A. H. Robins Co. is the sponsor of new NADA 141-003. A. H. Robins Co. filed a supplement to NADA 140-889 to provide for the establishment of a new NADA. Therefore, the agency is amending 21 CFR 524.1600a to reflect the change of sponsorship.

List of Subjects in 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 part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 524.1600a [Amended]

2. Section 524.1600a *Nystatin, neomycin, thiostrepton, and triamcinolone acetone ointment* is amended in paragraph (b) by removing "See Nos. 000031/000332 (cosponsors), 000069, 025463, 051259, and 053501 in § 510.600(c) of this chapter" and by adding in its place "See Nos. 000031, 000069, 000332, 025463, 051259, and 053501 in § 510.600(c) of this chapter".

Dated: November 21, 1996.

Robert C. Livingston,

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

[FR Doc. 96-30589 Filed 11-29-96; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 318

[DSWA Instruction 5400.11B]

Privacy Program

AGENCY: Defense Special Weapons Agency, DOD.

ACTION: Final rule.

SUMMARY: The Defense Special Weapons Agency (DSWA) is revising its procedural and exemptions rules for the DSWA Privacy Program.

EFFECTIVE DATE: November 9, 1996.

FOR FURTHER INFORMATION CONTACT: Mrs. Sandy Barker at (703) 325-7681.

SUPPLEMENTARY INFORMATION: The proposed rule was previously published on September 9, 1996 at 61 FR 47467.

No comments were received, therefore, DSWA is adopting the rule as final. Executive Order 12866. It has been determined that this Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of \$100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act. It has been determined that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act. It has been determined that this Privacy Act rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

List of Subjects in 32 CFR Part 318
Privacy.

Accordingly, 32 CFR part 318 is revised as follows:

PART 318—DEFENSE SPECIAL WEAPONS AGENCY PRIVACY PROGRAM

Sec.

318.1 Purpose and scope.

318.2 Applicability.

318.3 Designations and responsibilities.

318.4 Procedures for requests pertaining to individual records in a record system.

318.5 Disclosure of requested information to individuals.

318.6 Request for correction or amendment to a record.

318.7 Agency review of request for correction or amendment of record.

318.8 Appeal of initial adverse Agency determination for access, correction or amendment.

318.9 Exemptions rules.

Authority: Pub. L. 93-579, 88 Stat. 1896 (5 U.S.C. 552a).

§ 318.1 Purpose and scope.

(a) This rule implements the provisions of the Privacy Act of 1974, as amended, and adopts the policies and procedures as set forth by the Department of Defense Privacy Program, 32 CFR part 310.

(b) This rule establishes procedures whereby individuals can:

(1) Request notification of whether Defense Special Weapons Agency (DSWA) maintains or has disclosed a record pertaining to them in any nonexempt system of records;

(2) Request a copy or other access to such a record or to an accounting of its disclosure;

(3) Request that the record be amended; and

(4) Appeal any initial adverse determination of any such request.

(c) Specifies those system of records which the Director, Headquarters, Defense Special Weapons Agency has determined to be exempt from the procedures established by this rule and by certain provisions of the Privacy Act.

(d) DSWA policy encompasses the safeguarding of individual privacy from any misuse of DSWA records and the provides the fullest access practicable by individuals to DSWA records concerning them.

§ 318.2 Applicability.

The provisions of this rule apply to Headquarters, Defense Special Weapons Agency (HQ DSWA), and Field Command, Defense Special Weapons Agency (FC DSWA).

§ 318.3 Designations and responsibilities.

(a) The General Counsel, Headquarters, Defense Special Weapons

Agency, is designated as the Agency Privacy Act Officer.

(1) The Privacy Act Officer is the principal point of contact for privacy matters and is the Agency Initial Denial Authority.

(2) The Privacy Act Officer is responsible for monitoring and ensuring Agency compliance with the DoD Privacy Program in accordance with 32 CFR part 310.

(b) The Director, DSWA, is the Agency Appellate Authority.

(c) The Director, DSWA is responsible for implementing the Agency Privacy Act Program in accordance with the specific requirements of 32 CFR part 310.

(d) Agency component and element responsibilities are set forth in DSWA Instruction 5400.11B,¹ January 12, 1995.

§ 318.4 Procedures for requests pertaining to individual records in a record system.

(a) An individual seeking notification of whether a system of records, maintained by the Defense Special Weapons Agency, contains a record pertaining to himself/herself and who desires to review, have copies made of such records, or to be provided an accounting of disclosures from such records, shall submit his or her request in writing. Requesters are encourage to review the systems of records notices published by the Agency so as to specifically identify the particular record system(s) of interest to be accessed.

(b) In addition to meeting the requirements set forth in section 318.4 of this part, the individual seeking notification, review or copies, and an accounting of disclosures will provide in writing his or her full name, address, Social Security Number, and a telephone number where the requester can be contacted should questions arise concerning the request. This information will be used only for the purpose of identifying relevant records in response to an individual's inquiry. It is further recommended that individuals indicate any present or past relationship or affiliations, if any, with the Agency and the appropriate dates in order to facilitate a more thorough search. A notarized statement or an unsworn declaration in accordance with 28 U.S.C. 1746 may also be required.

(c) An individual who wishes to be accompanied by another individual when reviewing his or her records, must provide the Agency with written consent authorizing the Agency to

disclose or discuss such records in the presence of the accompanying individual.

(d) Individuals should mail their written request to the Office of General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310-3398 or to the office designated in the system notice and indicate clearly on the outer envelope 'Privacy Act Request'.

§ 318.5 Disclosure of requested information to individuals.

(a) The Defense Special Weapons Agency, upon receiving a request for notification of the existence of a record or for access to a record, shall acknowledge receipt of the request within 10 working days.

(b) Determine whether or not such record exists.

(c) Determine whether or not such request for access is available under the Privacy Act.

(d) Notify requester of determinations within 30 working days after receipt of such request.

(e) Provide access to information pertaining to that person which has been determined to be available within 30 working days.

(f) Notify the individual if fees will be assessed for reproducing copies of the records. Fee schedule and rules for assessing fees are contained in section 318.11 of this part.

§ 318.6 Request for correction or amendment to a record.

(a) An individual may request that the Defense Special Weapons Agency correct, amend, or expunge any record, or portions thereof, pertaining to the requester that he/she believe to be inaccurate, irrelevant, untimely, or incomplete.

(b) Such requests shall specify the particular portions of the records in question, be in writing and should be mailed to the Office of General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310-3398.

(c) The requester shall provide sufficient information to identify the record and furnish material to substantiate the reasons for requesting corrections, amendments, or expurgation.

§ 318.7 Agency review of request for correction or amendment of record.

(a) The Agency will acknowledge a request for correction or amendment within 10 working days of receipt. The acknowledgment will be in writing and will indicate the date by which the Agency expects to make its initial determination.

¹ Copies may be obtained from Office of General Counsel, Headquarters, Defense Special Weapons Agency, Washington, DC 20305-1000.

(b) The Agency shall complete its consideration of requests to correct or amend records within 30 working days, and inform the requester of its initial determination.

(c) If it is determined that records should be corrected or amended in whole or in part, the Agency shall advise the requester in writing of its determination; and correct or amend the records accordingly. The Agency shall then advise prior recipients of the records of the fact that a correction or amendment was made and provide the substance of the change.

(d) If the Agency determines that a record should not be corrected or amended, in whole or in part, as requested by the individual, the Agency shall advise the requester in writing of its refusal to correct or amend the records and the reasons therefor. The notification will inform the requester that the refusal may be appealed administratively and will advise the individual of the procedures for such appeals.

§ 318.8 Appeal of initial adverse Agency determination for access, correction or amendment.

(a) An individual who disagrees with the denial or partial denial of his or her request for access, correction, or amendment of Agency records pertaining to himself/herself, may file a request for administrative review of such refusal within 30 days after the date of notification of the denial or partial denial.

(b) Such requests shall be made in writing and mailed to the Office of the General Counsel, Defense Special Weapons Agency, 6801 Telegraph Road, Alexandria, VA 22310-3398.

(c) The requester shall provide a brief written statement setting for the reasons for his or her disagreement with the initial determination and provide such additional supporting material as the individual feels necessary to justify the appeal.

(d) Within 30 working days of receipt of the request for review, the Agency shall advise the individual of the final disposition of the request.

(e) In those cases where the initial determination is reversed, the individual will be so informed and the Agency will take appropriate action.

(f) In those cases where the initial determination is sustained, the individual shall be advised:

(1) In the case of a request for access to a record, of the individual's right to seek judicial review of the Agency refusal for access.

(2) In the case of a request to correct or amend the record:

(i) Of the individual's right to file a concise statement of his or her reasons for disagreeing with the Agency's decision in the record,

(ii) Of the procedures for filing a statement of the disagreement, and

(iii) Of the individual's right to seek judicial review of the Agency's refusal to correct or amend a record.

§ 318.9 Exemption rules.

(a) *Exemption for classified material.* All systems of records maintained by the Defense Special Weapons Agency shall be exempt under section (k)(1) of 5 U.S.C. 552a, to the extent that the systems contain any information properly classified under E.O. 12598 and that is required by that E.O. to be kept secret in the interest of national defense or foreign policy. This exemption is applicable to parts of all systems of records including those not otherwise specifically designated for exemptions herein which contain isolated items of properly classified information.

(b) *System identifier and name:* HDSWA 007, Security Operations.

(1) *Exemption:* Portions of this system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3), (d)(1) through (d)(4), (e)(1), (e)(4)(G), (H), (I), and (f).

(2) *Authority:* 5 U.S.C. 552a(k)(5).

(3) *Reasons:* (i) From subsection (c)(3) because it will enable DSWA to safeguard certain investigations and relay law enforcement information without compromise of the information, and protect the identities of confidential sources who might not otherwise come forward and who have furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(ii) From subsection (d)(1) through (d)(4) and (f) because providing access to records of a civil investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of security investigations. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim

growing out of the investigation or proceeding.

(iii) From subsection (e)(1), (e)(4)(G), (H), (I) because it will provide protection against notification of investigatory material including certain reciprocal investigations and counterintelligence information, which might alert a subject to the fact that an investigation of that individual is taking place, and the disclosure of which would weaken the on-going investigation, reveal investigatory techniques, and place confidential informants in jeopardy who furnished information; under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(d) *System identifier and name:* HDSWA 011, Inspector General Investigation Files.

(1) *Exemption:* Portions of this system of records may be exempt from the provisions of 5 U.S.C. 552a(c)(3); (d)(1) through (4); (e)(1); (e)(4)(G), (H), and (I); and (f).

(2) *Authority:* 5 U.S.C. 552a(k)(2).

(3) *Reasons:* (i) From subsection (c)(3) because it will enable DSWA to conduct certain investigations and relay law enforcement information without compromise of the information, protection of investigative techniques and efforts employed, and identities of confidential sources who might not otherwise come forward and who furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise.)

(ii) From subsection (d)(1) through (d)(4) and (f) because providing access to records of a civil investigation and the right to contest the contents of those records and force changes to be made to the information contained therein would seriously interfere with and thwart the orderly and unbiased conduct of the investigation and impede case preparation. Providing access rights normally afforded under the Privacy Act would provide the subject with valuable information that would allow interference with or compromise of witnesses or render witnesses reluctant to cooperate; lead to suppression, alteration, or destruction of evidence; and result in the secreting of or other disposition of assets that would make them difficult or impossible to reach in order to satisfy any Government claim growing out of the investigation or proceeding.

(iii) From subsection (e)(1), (e)(4)(G), (H), and (I) because it will provide protection against notification of

investigatory material including certain reciprocal investigations and counterintelligence information, which might alert a subject to the fact that an investigation of that individual is taking place, and the disclosure of which would weaken the on-going investigation, reveal investigatory techniques, and place confidential informants in jeopardy who furnished information under an express promise that the sources' identity would be held in confidence (or prior to the effective date of the Act, under an implied promise).

Dated: November 25, 1996.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 96-30535 Filed 11-29-96; 8:45 am]

BILLING CODE 5000-04-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 110

[CGD07-96-017

RIN 2115-AA98

Anchorage Areas; Ashley River, Charleston, SC; Correction

AGENCY: Coast Guard, DOT.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to the final regulations [FR Doc. 96-20018], which were published Wednesday, August 7, 1996, (61 FR 40993). The regulations related to the establishment of anchorage areas on the Ashley River, Charleston, South Carolina.

EFFECTIVE DATE: September 6, 1996.

FOR FURTHER INFORMATION CONTACT: CWO4 R.M. Webber, Project Officer, Marine Safety Office Charleston, Tel: (803) 724-7690.

SUPPLEMENTARY INFORMATION:

Need for Correction

As published, the final regulations contain an error which requires correction for the proper establishment of the anchorage areas.

Correction of Publication

Accordingly, the publication on August 7, 1996, (61 FR 40993) of the final regulations [FR Doc. 96-20018], is corrected as follows:

§ 110.72d [Corrected]

On page 40994, in the second column, in § 110.72d, in paragraph (a), in the

seventh line, "32°46'43.7"N" is corrected to read "32°46'42.7"N".

Dated: October 25, 1996.

J.W. Lockwood,

U.S. Coast Guard Commander, Seventh Coast Guard District.

[FR Doc. 96-30067 Filed 11-29-96; 8:45 am]

BILLING CODE 4910-14-M

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 251, 252, 257, and 259

[Docket No. RM 94-1A]

Copyright Arbitration Royalty Panels; Rules and Regulations

AGENCY: Copyright Office, Library of Congress.

ACTION: Technical amendments.

SUMMARY: On December 7, 1994, the Copyright Office of the Library of Congress published final regulations governing the administration of royalty fee distribution proceedings and royalty rate adjustment proceedings for the statutory licenses. Over the past eighteen months, the Office tested these rules and identified areas which required minor adjustments or clarification. This notice makes non-substantive technical amendments to correct the identified problems.

EFFECTIVE DATE: January 2, 1997.

FOR FURTHER INFORMATION CONTACT: Marilyn J. Kretsinger, Acting General Counsel, or Tanya M. Sandros, CARP Specialist, Copyright Arbitration Royalty Panel, P.O. Box 70977, Southwest Station, Washington, D.C. 20024. Telephone: (202) 707-8380. Telefax: (202) 707-8366.

SUPPLEMENTARY INFORMATION: The Copyright Office ("Office") of the Library of Congress issued the current regulations, see 37 CFR chapter II, subchapter B, governing the Copyright Arbitration Royalty Panels ("CARP") after an extensive rulemaking which began with a notice of proposed rulemaking, 59 FR 2550 (January 18, 1994), and concluded with the publication of the final regulations on December 7, 1994. 59 FR 63025 (December 7, 1994). During 1995 and 1996, these rules were used to conduct a CARP proceeding to determine the distribution of the 1990, 1991, and 1992 cable royalties; to initiate a second CARP proceeding to determine the distribution of the 1992, 1993, and 1994 digital audio recording technology (DART) royalties in the Musical Works

Funds; and to set the schedule for four rate setting proceedings.

In using the CARP rules to administer these proceedings, the Office identified some minor problems with the application of the current rules, which these non-substantive technical amendments correct. The amendments clarify ambiguous sections, harmonize discordant rules, and streamline the process, when possible, based on the experience gleaned over the past eighteen months.

Official Address

During the course of a CARP proceeding, interested parties file pleadings with the Copyright Office and the CARP. Although many of these pleadings are filed with the Copyright Office prior to the initiation of the CARP, the regulations do not instruct the parties where to file the pleading at the Copyright Office, if hand delivered. Therefore, § 251.1 is amended to address this omission by adding the official address of the Office of the Copyright General Counsel.

List of Arbitrators

The Librarian of Congress selects arbitrators for a CARP from a list of names generated from the nominations submitted to him by at least three professional arbitration associations. Section 251.3(a) allows the arbitration associations to submit new names each year and § 251.3(b) requires the Librarian to publish a list of qualified nominees after January 1 of each year.

The annual solicitation of new names from at least three arbitration associations and the review of the financial disclosure forms from the nominees, however, requires substantial time and effort on the part of the Librarian of Congress, the Copyright Office, and the nominating organizations. Likewise, the parties to a proceeding expend considerable time and expense in examining the background material for each potential arbitrator in preparing their objections under § 251.4 to listed arbitrators. But in spite of all the preliminary work, very few individuals on the list actually will have an opportunity to serve on a panel. In 1995, three individuals from a list of 77 names were chosen to serve on a single panel; and this year, no more than six individuals from a list of 36 nominees will be chosen to serve as a CARP arbitrator.

In consideration of the relatively small probability of using more than a handful of names from the list in any given year, the Office cannot justify the disproportionate amount of time and expense expended by the nominating