

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Soluble Powder

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 I. D. Russell Co. Laboratories. The ANADA provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and broiler chickens for the control of necrotic enteritis.

EFFECTIVE DATE: December 10, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: I. D. Russell Co. Laboratories, 1301 Iowa Ave., Longmont, CO 80501, filed ANADA 200-189 that provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. Approval of I. D. Russell Co. Laboratories' ANADA 200-189 lincomycin hydrochloride soluble powder is as a generic copy of Pharmacia & Upjohn's NADA 111-636 Lincomix™ soluble powder. The ANADA is approved as of November 7, 1997, and the regulations are amended in 21 CFR 520.1263c(b) 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 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(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.

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: 21 U.S.C. 360b.

§ 520.1263c [Amended]

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by removing "No. 000009" and adding in its place "Nos. 000009 and 017144".

Dated: December 1, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97-32217 Filed 12-9-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 320

National Imagery and Mapping Agency (NIMA) Privacy Program

AGENCY: Department of Defense.

ACTION: Final rule.

SUMMARY: The document is published to make administrative changes to the National Imagery and Mapping Agency (NIMA), formerly known as the Defense Mapping Agency, Privacy Program rule.

EFFECTIVE DATE: This rule is effective December 10, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. M. Flattery, 301-227-2268.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 320

Privacy program.
Accordingly, 32 CFR part 320 is amended as follows:

PART 320—NATIONAL IMAGERY AND MAPPING AGENCY (NIMA) PRIVACY PROGRAM

1. The authority citation for part 320 continues to read as follows:

Authority: Pub. L. 93-579, 88 Stat. 1986 (5 U.S.C. 552a).

2. The part heading is revised as set forth above.

§ 320.1 [Amended]

3. In § 320.1, paragraph (a)(1)(i) is amended by revising "Defense Mapping Agency (DMA)" to read "National Imagery and Mapping Agency (NIMA)" and paragraph (a)(2) is amended by revising "DMS" to read "NIMA."

§ 320.2 [Amended]

4. In § 320.2, the definitions *Record* and *System or records* are amended by revising "DMA" to read "NIMA."

5. Section 320.3 is amended as follows:

a. Paragraph (a), paragraph (c)(2), and paragraph (d) by revising "DMA" to read "NIMA";

b. Paragraph (b) by revising "HQ DMA or at the principal office of DMA Component (Please refer to the DMA address list at paragraph (e) of this section)" to read "NIMA General Counsel Office (refer to the NIMA address list at paragraph (e) of this section) or at the NIMA officer";

c. Paragraph (c) introductory text by revising "Director of the DMA Component or Staff Office" to read "Office of General Counsel," and after the word "section)" and "or NIMA office";

d. Paragraph (e) is revised to read as follows:

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

* * * * *

(e) NIMA General Counsel address list.

(1) NIMA Fairfax, Attn: GC, Mail Stop A-7 NIMA Fairfax, 8613 Lee Highway, Fairfax, VA 22031-2137.

(2) NIMA Bethesda, Attn: GCM, Mail Stop D-10, 4600 Sangamore Road, Bethesda, MD 20816-5003.

(3) NIMA St. Louis, Attn: GCM Mail Stop L-32, 3200 South Second Street, St. Louis, MO 63118-3399.

(4) NIMA Navy Yard, Attn: GCM Stop, N-24, Building 213, Washington, DC 20505-0001.

(5) NIMA Westfields, Attn: GCM, Room 13F20C, 14675 Lee Road, Chantilly, VA 20151-1715.

6. Section 320.4 is amended as follows:

a. Paragraph (a), paragraph (b) introductory text, paragraph (b)(3), paragraph (c)(2), and paragraph (d) by revising "DMA" to read "NIMA";

b. Paragraph (b)(1) is amended by revising "Headquarters Defense Mapping Agency or at the principal

office of the DMA Component" to read "Office of General Counsel", and after the word "list)" and "or at the NIMA office"; and paragraph (b)(2) is amended by revising "Director Defense Mapping Agency, or at the Director of the DMA Component" to read "General Counsel (refer to § 320.3(e) for address list) or to the NIMA officer";

c. The heading of paragraph (c), paragraph (c)(1) introductory text, and paragraph (c)(1)(iv) are revised to read as follows:

§ 320.4 Disclosure of requester information to individuals.

(c) *NIMA determination of requests for access.* (1) Upon receipt of a request made in accordance with this section, the NIMA Office of the General Counsel or NIMA office having responsibility for maintenance of the record in question shall release the record, or refer it to an Initial Denial Authority, who shall:

(iv) Requests for access to personal records may be denied only by an agency official authorized to act as an Initial Denial Authority or Final Denial Authority, after coordination with the Office of General Counsel.

§ 320.5 [Amended]

7. In § 320.5, paragraph (b) is amended by revising "Staff Director of the DMA Headquarters or Component Staff Element" to read "NIMA Office of General Counsel or NIMA office".

8. Section 320.6 is amended by revising paragraph (a) and paragraph (b) to read as follows:

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

(a) Not later than 10 working days after receipt of a request to amend a record, in whole or in part, the NIMA Office of General Counsel, or NIMA office having responsibility for maintenance of the record in question shall make any correction of any portion of the record which the individual believes is not accurate, relevant, timely or complete and thereafter inform the individual of such correction or process the request for refusal.

(b) Refusals of requests for amendment of a record will be made only by an agency official authorized to act as an Initial Denial Authority or Final Denial Authority, after coordination with the Office of General Counsel. The refusal letter will inform the individual by certified mail, return receipt requested, of refusal to amend the record setting forth the reasons therefor and notifying the individual of

his right to appeal the decision to the Director, NIMA, in accordance with § 320.7.

§ 320.7 [Amended]

9. In § 320.7, paragraph (b) is amended by revising "Director, Defense Mapping Agency" to read "Director, NIMA" and "Headquarters, Defense Mapping, Building 56, U.S. Naval Observatory, Washington, DC 20305." to read "NIMA, Attn: Mail Stop D-10, 4600 Sangamore Road, Bethesda, MD 20816-5003."; paragraph (c) introductory text is amended by revising "Defense Mapping Agency" to read "NIMA, or his designee"; and paragraphs (c)(1) and (d) are amended after the word "Director" by adding "or his designee".

§ 320.8 [Amended]

10. Section 320.8 is amended in paragraph (a) and paragraph (c)(5) by revising "DMA" to read "NIMA"; paragraph (c)(3) by revising "§ 295.2" to read "Appendix C to 32 CFR part 310"; paragraph (c)(7) by revising "Defense Mapping Agency" to read "NIMA".

§ 320.9 [Amended]

11. Section 320.9 paragraph (b)(2)(i) and paragraph (b)(3), are amended by revising "DMA" to read "NIMA".

§ 320.10 [Amended]

12. Section 320.10 is amended by revising "DMA" to read "NIMA".

§ 320.11 [Amended]

13. Section 320.11 is amended by revising "Defense Mapping Agency" to read "NIMA".

Dated: December 4, 1997.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 97-32224 Filed 12-9-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-97-062]

RIN 2115-AE46

Special Local Regulations; Puerto Rico PRO-TOUR Offshore Race, Fajardo, PR

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Special Local Regulations are being adopted for the Puerto Rico PRO-

TOUR Offshore Race. The event will be held from 1 p.m. to 2:30 p.m. Atlantic Standard Time (AST) on December 14, 1997 in the waters of Rada Fajardo, due East of Villa Marine, Fajardo, Puerto Rico. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations become effective from 11:30 a.m. to 3:30 p.m. AST, December 14, 1997.

FOR FURTHER INFORMATION CONTACT: LT. D. L. GARRISON at (787) 729-6800, ext. 227.

SUPPLEMENTARY INFORMATION:

Background and Purpose

The event requiring these regulations is the Puerto Rico PRO-TOUR Offshore Race. These will be 20 high speed offshore power boats racing on a fixed course offshore Fajardo, Puerto Rico. The race boats will be competing at high speeds with numerous spectator craft in the area, creating an extra or unusual hazard in the navigable waterways. These regulations are required to provide for the safety of life on the navigable waters during the running of the PRO-TOUR Offshore Race.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for these regulations and good cause exists for making them effective in less than 30 days from the date of publication. The permit application was received by the unit less than six weeks before the scheduled date for the event.

Regulatory Evaluation

This regulation is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(f) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulated policies and procedures of DOT is unnecessary.. Entry into this area is prohibited for only 4 hours on the day of the event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include small