under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at anytime on or before December 3, 1998, file with the Dockets Management Branch (address above) written objection thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated August 29, 1996, from the Chemistry Review Branch (HFS–247), to the file concerning FAP 6B4512, dietary concentrations of the additive and the impurity (*para*-chloroaniline).

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger and J. K. Marquis, published by S. Karger, New York, NY, pp. 24–33, 1985.

3. Chhabra, R. S., Toxicology and Carcinogenesis Studies of *para*-Chloroaniline Hydrochloride in F344/N Rats and B6C3F1 Mice (Gavage Studies), National Toxicology Program, Technical Report Series No. 351, July 1989.

4. Report of the Quantitative Risk Assessment Committee, FDA, concerning ''Assessment of Carcinogenic upper-bound lifetime risk resulting from contamination by *para*-chloroaniline residues in C.I. Pigment Red 202 (Ciba-Geigy Corp.), FAP 6B4512, dates April 9, 1998.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding an entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
2,9-Dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202, CAS Reg. No. 3089–17–6).	For use at levels not to exceed 1.0 percent by weight of polymers.
* * *	* * * *

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29333 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate Sodium

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 a supplemental new animal drug application (NADA) filed by Anika Therapeutics, Inc. The supplemental NADA provides for equine use of hyaluronate sodium injection containing 11 milligrams hyaluronate sodium per milliliter (mg/mL) rather than the currently approved 10 mg/mL.

EFFECTIVE DATE: November 3, 1998.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Jr., Center For Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–4105.

SUPPLEMENTARY INFORMATION: Anika Therapeutics, Inc., 236 West Cummings Park, Woburn, MA 01810, formerly Anika Research, Inc., 160 New Boston St., Woburn, MA 01801, filed supplemental NADA 122–578 that provides for equine use of a 11-mg/mL Hyvisc (hyaluronate sodium) injection instead of the currently approved 10-mg/mL injection. The injection is for intra-articular use in horses for treatment of joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of September 30, 1998, and 21 CFR 522.1145 is amended in paragraph (a)(2) and by adding paragraph (f) to reflect the approval.

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 supplemental 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, except Federal holidays.

In addition, the sponsor has changed its name and address. The regulations are amended in 21 CFR 510.600(c) to

reflect the changes in sponsor name and address.

FDA 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

21 CFR Part 510

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

21 CFR Part 522

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 parts 510 and 522 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) in the entry ''Anika Research, Inc.'' and in paragraph (c)(2) in the entry ''060865'' by removing the sponsor name and address and inserting in its place ''Anika Therapeutics Inc., 236 West Cummings Park, Woburn, MA 01801''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

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

4. Section 522.1145 is amended by revising paragraph (a)(2) and adding paragraph (f) to read as follows:

§ 522.1145 Hyaluronate sodium injection.

(a) * * *

(2) *Sponsor.* See 000009 in § 510.600(c).

* * * * *

(f)(1) *Specifications.* Each milliliter of sterile aqueous solution contains 11 milligrams of hyaluronate sodium.

(2) *Sponsor.* See 060865 in § 510.600(c).

(3) *Conditions of use*—(i) *Amount.* Small and medium-size joints (carpal, fetlock)—22 milligrams; larger joint (hock)—44 milligrams.

(ii) *Indications for use.* Treatment of joint dysfunction in horses due to noninfectious synovitis associated with equine osteoarthritis.

(iii) *Limitations.* For intra-articular injection in horses only. Treatment may be repeated at weekly intervals for a total of three treatments. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: October 25, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–29332 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F11

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Carbadox

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 a supplemental new animal drug application (NADA) filed by Pfizer Animal Health, Inc. The supplemental NADA provides for the establishment of a 42-day slaughter withdrawal period for use of carbadox in swine feed.

EFFECTIVE DATE: November 3, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1652.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is sponsor of NADA 41–061 that provides for the use of Mecadox® 10 (carbadox) Type A medicated article used to make Type B and Type C medicated swine feeds. Mecadox® is indicated for the control of bacterial swine enteritis, increased rate of weight gain, and improved feed efficiency. The sponsor filed a supplemental NADA that provides for the establishment of a withdrawal period of 42 days in swine and a limitation against use in pregnant swine or swine intended for breeding purposes. The supplemental NADA is approved as of October 5, 1998, and the regulations are amended in 21 CFR 558.115(d)(1)(ii) and (d)(2)(ii) to reflect the approval. The basis for 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, 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.

List of Subjects in 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 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.

2. Section 558.115 is amended by revising paragraphs (d)(1)(ii) and (d)(2)(ii) to read as follows:

§ 558.115 Carbadox.

* * * * *

(d) * * *

(1) * * *

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

(2) * * *

(ii) *Limitations.* Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

* * * * *

Dated: October 25, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–29334 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F