Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ''Pharmacopeial Forum,'' The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 693 to 694, 717 to 719, and 726 to 729, May and June, 2000.

2. ''Third Supplement,'' United States Pharmacopeia 24, National Formulary 19, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 3025, 3053, 3061 to 3062, January 2, 2001.

List of Subjects in 21 CFR 352

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 352 is amended as follows:

PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 352 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 352.10 is amended by revising paragraphs (f) through (n) to read as follows:

§ 352.10 Sunscreen active ingredients.

* * * * *

(f) Ensulizole up to 4 percent.

(g) Homosalate up to 15 percent.

(h) [Reserved].

(i) Meradimate up to 5 percent.

(j) Octinoxate up to 7.5 percent.

(k) Octisalate up to 5 percent.

(l) Octocrylene up to 10 percent.

(m) Oxybenzone up to 6 percent.

(n) Padimate O up to 8 percent.

* * * * *

3. Section 352.20 is amended by revising paragraphs (a)(1) and (a)(2) as follows:

§ 352.20 Permitted combinations of active ingredients.

* * * * *

(a) *Combinations of sunscreen active ingredients.* (1) Two or more sunscreen active ingredients identified in § 352.10(a), (c), (e), (f), (g), and (i) through (r) may be combined with each other in a single product when used in the concentrations established for each ingredient in § 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

(2) Two or more sunscreen active ingredients identified in § 352.10(b), (c), (e), (g), (j) through (m), (o), and (q) may be combined with each other in a single product when used in the concentrations established for each ingredient in § 352.10. The concentration of each active ingredient must be sufficient to contribute a minimum SPF of not less than 2 to the finished product. The finished product must have a minimum SPF of not less than the number of sunscreen active ingredients used in the combination multiplied by 2.

* * * * *

Dated: June 11, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15632 Filed 6–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 529

Certain Other Dosage Form New Animal Drugs; Progesterone Intravaginal Inserts

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 new animal drug application (NADA) filed by DEC International, Inc. The NADA provides for use of progesterone intravaginal inserts for manipulation of estrus in cattle.

DATES: This rule is effective June 20, 2002.

FOR FURTHER INFORMATION CONTACT: Harlan J. Howard, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0231, e-mail: hhoward@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison WI 53708–8050, filed NADA 141–200 that provides for use of EAZI–BREED CIDR Progesterone Intravaginal Inserts for synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers. The NADA is approved as of May 2, 2002, and the regulations in 21 CFR part 529 are amended by adding § 529.1940 to reflect the approval. The regulation in 21 CFR 522.690 is being amended to add a cross-reference for the concurrent use of dinoprost solution by intramuscular injection and is being revised to reflect a current format. The basis of approval is discussed in the freedom of information summary.

In addition, DEC International, Inc., has not been previously listed in the animal drug regulations as a sponsor of an approved application. At this time, 21 CFR 510.600(c) is being amended to add entries for the firm.

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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning May 2, 2002.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 522 and 529

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, 522, and 529 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.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding an entry for ''DEC International, Inc.'' and in the table in paragraph (c)(2) by numerically adding an entry for ''067080'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	* *
DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison, WI 53708–8050	067080
* * * * *	* *

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
067080	DEC International, Inc., 1919 South Stoughton Rd., P.O. Box 8050, Madison, WI 53708–8050
* * * * * * *	

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 522.690 is revised to read as follows:

§ 522.690 Dinoprost solution.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to 5 milligrams (mg) dinoprost.

(b) *Sponsors.* See Nos. 000009 and 059130 in § 510.600(c) of this chapter.

(c) *Special considerations.* (1) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and bronchiospasms. Accidental spillage on the skin should be washed off immediately with soap and water.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount.* 1 mg per 100 pounds of body weight as a single intramuscular injection.

(ii) *Indications.* For its luteolytic effect to control timing of estrus in estrus cycling mares and in clinically anestrous mares that have a corpus luteum.

(iii) *Limitations.* Not for use in horses intended for food.

(2) *Cattle*—(i) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as an intramuscular injection either once or twice at a 10- to 12-day interval.

(B) *Indications.* For its luteolytic effect to control timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(ii) *Beef cattle and nonlactating dairy heifers*—(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of pyometra (chronic endometritis).

(iii) *Nonlactating cattle*—(A) *Amount.* 25 mg as a single intramuscular injection during the first 100 days of gestation.

(B) *Indications.* For its abortifacient effect in nonlactating cattle.

(iv) *Lactating dairy cattle*—(A) *Amount.* 25 mg as a single intramuscular injection.

(B) *Indications.* For treatment of unobserved (silent) estrus in lactating dairy cattle that have a corpus luteum.

(v) Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter may be used concurrently with progesterone intravaginal inserts as in § 529.1940 of this chapter.

(3) *Swine*—(i) *Amount.* 10 mg as a single intramuscular injection.

(ii) *Indications.* For parturition induction in swine when injected within 3 days of normal predicted farrowing.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 529 continues to read as follows:

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

6. Section 529.1940 is added to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

(a) *Specifications.* Each insert contains 1.38 grams of progesterone in molded silicone over a nylon spine.

(b) *Sponsor.* See No. 067080 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.540(a) of this chapter.

(d) *Special considerations.* (1) Wear latex gloves when handling inserts. Store removed inserts in a plastic bag or other sealable container until they can be disposed in accordance with applicable local, State, and Federal regulations.

(2) This product is approved with the concurrent use of dinoprost solution on day 6 of the 7-day administration period. See § 522.690(c) of this chapter.

(e) *Conditions of use*—(1) *Amount.* Administer one intravaginal insert per animal for 7 days. Administer 25 milligrams (mg) dinoprost (5 milliliters (mL) of 5 mg/mL solution as in § 522.690(a) of this chapter) 1 day prior to insert removal.

(2) *Indications for use.* For synchronization of estrus in suckled beef cows and replacement beef and dairy heifers, for advancement of first postpartum estrus in suckled beef cows, and for advancement of first pubertal estrus in replacement beef heifers.

(3) *Limitations.* Do not use in animals with abnormal, immature, or infected genital tracts; or in beef cows that are fewer than 20 days postpartum; or in beef or dairy heifers of insufficient size or age for breeding; or in lactating dairy cows. Do not use an insert more than once. To prevent the potential transmission of venereal and bloodborne diseases, the inserts should

be disposed after a single use. Administration of vaginal inserts for periods greater than 7 days may result in reduced fertility. Dinoprost solution as provided by No. 000009 in § 510.600(c) of this chapter.

Dated: June 6, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–15633 Filed 6–19–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 926

[SPATS No. MT–021–FOR]

Montana Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving a proposed amendment to the Montana abandoned mine land reclamation (AMLR) plan (hereinafter referred to as the ''Montana plan'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Montana proposed revisions and additional explanatory information about the Department of Environmental Quality (DEQ), its authority, organization, personnel staffing policies, and purchasing and procurement policies. Montana also provided information about the AMLR plan, the goals and objectives of the emergency program, reclamation project ranking and selection, the coordination among agencies, policies and procedures for land acquisition, reclamation of private land, consent for entry, the accounting system, and a new appendix concerning the abandoned inactive mines scoring system (AIMSS). Montana revised its plan to meet the requirements of the corresponding Federal regulations and to be consistent with SMCRA, to clarify ambiguities, and to improve operational efficiency.

EFFECTIVE DATE: June 20, 2002.

FOR FURTHER INFORMATION CONTACT: Guy Padgett, Director, Casper Field Office; Telephone: (307) 261–6550; Internet address: gpadgett@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Montana Plan

The AMLR Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee which is collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a ''plan'') for the reclamation of abandoned coal mines.

On November 24, 1980, the Secretary of the Interior approved the Montana plan. You can find general background information on the Montana plan, including the Secretary's findings and the disposition of comments, in the October 24, 1980, **Federal Register** (45 FR 70445). You can also find later actions concerning Montana's plan and plan amendments at 30 CFR 926.21 and 926.25.

II. Submission of the Proposed Amendment

By letter dated August 15, 2000, Montana sent us a proposed amendment to its plan (SPATS No. MT–021–FOR, Administrative Record No. MT–18–01) under SMCRA (30 U.S.C. 1201 *et seq.*). Montana sent the amendment in response to a required plan amendment at 30 CFR 926.21(a) and at its own initiative.

Montana proposed to delete its abandoned mine land (AML) rule definitions of ''abandoned mine land reclamation fund,'' ''emergency,'' and ''extreme danger'' at the Administrative Rules of Montana (ARM) 26.4.301 and its definitions of ''abandoned mine land reclamation fund,'' ''emergency,'' ''expended,'' ''extreme danger,'' ''fund,'' ''left or abandoned in either an unreclaimed or inadequately reclaimed condition,'' ''Montana abandoned mine reclamation program,'' and ''reclamation activities'' at ARM 26.4.1231. Montana proposed a revised definition of ''abandoned'' at ARM 26.4.301 and a revised ARM 26.4.1303. Montana also proposed to delete the AML rules at ARM 26.4.1232 through 26.4.1242 and to rely instead on its AMLR plan and on the statutory provisions at the Montana Code Annotated (MCA) 82–4–239, 242, 323, 371, 372, 424, 445 and 446. Montana proposed revisions to MCA 82–4–239 to reflect the reorganized duties of the Board of Environmental Review and the DEQ. Montana presented its 1995 reorganization plan abolishing the Department of State Lands and creating the DEQ.

We announced receipt of the proposed amendment in the September 25, 2000, **Federal Register** (65 FR 57581; Administrative Record No. MT–18–06). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on October 25, 2000. We received comments from three Federal agencies.

During our review of the amendment, we identified concerns relating to the deletion of Montana's rules concerning non-emergency AML reclamation, the deletion of Montana's rules concerning emergency reclamation, the statutes relating to Montana's AMLR plan, cross-references and quotes in the Montana plan which cited the deleted rules, and the reference to the former Department of State Lands, now the DEQ. We notified Montana of these concerns by letter dated January 24, 2001 (Administrative Record No. MT–18–08).

Montana responded in a letter dated April 30, 2001, by submitting additional explanatory information and a revised 2001 plan amendment (Administrative Record No. MT–18–11). Montana responded to each of our January 24, 2001, concerns, in particular, explaining where Montana believes it retains authority to implement its approved AMLR program (both emergency and non-emergency reclamation activities) for each deleted rule, where Montana intends to rely upon Federal authority, that the 2001 plan amendment supercedes earlier plans which may conflict with subsequent revisions, and referencing additional statutes which provide AML authority. Montana revised the AMLR plan to provide 2001 updated information, delete obsolete rule cites, change the State agency name to the Department of Environmental Quality, provide missing pages, provide an organizational chart for the DEQ, and make other editorial changes. By letter dated June 5, 2001 (Administrative Record No. MT–18–13), Montana provided a complete Attachment C to its revised plan.

Based on Montana's explanatory information and revised 2001 plan amendment, we reopened the public comment period in the June 1, 2001,