was republished in FAA Order 7400.8J, dated September 20, 2001.

This regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since it has been determined that this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1D, Policies and Procedures for Considering Environmental Impacts. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.43 [Amended]

2. Section 73.43 is amended as follows:

* * * * *

R–4305 Lake Superior, MN [Amended]

By removing the words ''Using Agency. USAF, Detachment 1, HQ Air Combat Command (DOSR), Offutt AFB, NE'' and inserting the words ''Using Agency. USAF, 55th Wing, Offutt AFB, NE.''

* * * * *

Issued in Washington, DC, on June 14, 2002.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 02–15601 Filed 6–19–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 352

[Docket No. 78N–0038]

RIN 0910–AA01

Sunscreen Drug Products for Over-the-Counter Human Use; Final Monograph; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that established conditions under which over-the-counter (OTC) sunscreen drug products are generally recognized as safe and effective and not misbranded. This amendment updates the monograph to incorporate United States Pharmacopeia (U.S.P.) name changes for four active ingredients included in the monograph. This final rule is part of FDA's ongoing review of OTC drug products.

DATES: This final rule is effective September 1, 2002. Submit written or electronic comments by August 19, 2002.

ADDRESSES: Submit written or electronic comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: John D. Lipnicki, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 21, 1999 (64 FR 27666), FDA issued a final monograph for OTC sunscreen drug products (21 CFR part 352). Section 352.10 of that monograph included the active ingredients menthyl anthranilate, octyl methoxycinnamate, octyl salicylate, and phenylbenzimidazole sulfonic acid.

In 2000 (Ref. 1), the U.S.P. proposed (for inclusion in the Third Supplement to U.S.P. 24) name changes for these four ingredients based on names adopted by the United States Adopted Names (USAN) Council. The new names are: Meradimate for menthyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. These name changes became official on March 1, 2001, and were subsequently included in the U.S.P. with an effective date of September 1, 2002 (Ref. 2).

II. Naming Process

The Federal Food, Drug, and Cosmetic Act (the act) requires the label of a drug to bear the established name of the drug to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula) (21 U.S.C. 352(e)(1)(A)(i)). The established name of the drug is defined as:

(A) the applicable official name designated pursuant to section 508 [of the Act], or (B) if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient * * *.

21 U.S.C. 352(e)(3)

Section 508 of the act (21 U.S.C. 358) authorizes FDA to designate an official name for any drug if FDA determines ''that such action is necessary or desirable in the interest of usefulness and simplicity'' (21 U.S.C. 358(a)). FDA does not, however, routinely designate official names for drug products under section 508 of the act (§ 299.4(e) (21 CFR 299.4(e))). In the absence of designation by FDA of an official name, interested persons may rely on the current compendial name as the established name (§ 299.4(e)).

III. The Technical Amendment

FDA has not designated official names for the following active ingredients: Menthyl anthranilate, octyl methoxycinnamate, octyl salicylate, and phenylbenzimidazole sulfonic acid. Thus, their established names are the current compendial names. The U.S.P. has now changed the compendial names to: Meradimate for menthyl anthranilate, octinoxate for octyl methoxycinnamate, octisalate for octyl salicylate, and ensulizole for phenylbenzimidazole sulfonic acid. To be consistent with the change in official compendial names, the agency is changing these names in § 352.10 in the

ingredient listing and in § 352.20 in the permitted combinations listing. Because the active ingredients are listed in alphabetical order in § 352.10, the ingredients listed in paragraphs (f) through (n) are rearranged because of these name changes. These name changes will become effective on September 1, 2002, to coincide with the U.S.P. effective date.

Because section 502(e)(1) and (e)(3) of the act (21 U.S.C. 352(e)(1) and (e)(3)) require the established name of a drug to be used, any sunscreen drug product initially introduced or initially delivered for introduction into interstate commerce after September 1, 2002, will need to bear the new established names ''meradimate,'' ''octinoxate,'' ''octisalate,'' and ''ensulizole.''

To the extent that 5 U.S.C. 553 applies to this action, it is exempt from notice and comment because it constitutes a rule of agency procedure under 5 U.S.C. 553(b)(3)(A). Alternatively, the agency's implementation of this action without opportunity for public comment comes within the good cause exceptions in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to public interest. This labeling revision represents a minor clarifying change that does not change the substance of the labeling requirements contained in the final regulations. As discussed above, manufacturers must relabel their products as a result of the U.S.P. name change to remain in compliance with the act. This amendment updates the names of four active ingredients in the final monograph for OTC sunscreen drug products to reflect this official name change that has already been implemented by the U.S.P. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether the regulation should be modified or revoked.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. FDA has determined that the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

The purpose of this final rule is to update the final monograph for OTC sunscreen drug products to incorporate U.S.P. name changes for four active ingredients included in the monograph. As discussed in section II of this document, section 502(e)(1) and (e)(3) of the act require that the established name of a drug be used. Under § 299.4(e), because FDA does not routinely designate official names under section 508 of the act, the established name under section 502(e) of the act ordinarily is the compendial name of the drug. Therefore, because FDA has not designated an official name under section 508 of the act, manufacturers must relabel their products as a result of the U.S.P. name change to remain in compliance with the act. Updating the names of the active ingredients in the sunscreen monograph to reflect their current established names will eliminate possible confusion by the public. The U.S.P. allows manufacturers 18 months to comply with the name changes, and the agency's effective date coincides with that of the U.S.P.

Because manufacturers must relabel their products as a result of the U.S.P. name change to remain in compliance with the act, this rule does not impose any additional costs on industry. Consequently, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, no further analysis is required.

V. Paperwork Reduction Act of 1995

The agency concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Opportunity for Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments by August 19, 2002. Two copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Dockets

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: