significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. Further, since this final rule makes no mandates on government entities and will result in expenditures less than $100 million in any one year, FDA need not prepare additional analyses under the Unfunded Mandates Reform Act.

The purpose of this final rule is to establish that OTC anorectal drug products containing a combination of hydrocortisone and pramoxine HCl are not generally recognized as safe and effective. Because no such products are currently marketed OTC, the final rule will not have an economic impact on any entity (no reformulations or relabeling are necessary) and will not require any new reporting or recordkeeping activities.

The agency has no alternative course of action as the data are inadequate to support monograph status for this combination product. Therefore, no additional professional skills are needed. The Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. 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.

VI. 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.

VII. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, in Docket No. 1980N–0050 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. HER1.
2. LET26.
3. Comment No. C25.
4. OTC vol. 12FR3.

List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

■ 2. Section 310.545 is amended by adding paragraph (a)(26)(xi), by revising paragraph (d) introductory text, by revising paragraph (d)(13), and by adding paragraph (d)(37) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) * * *

(26) * * *

(xi) *Combination drug products.* Any combination drug product containing hydrocortisone and pramoxine hydrochloride.

* * * * *

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(37) of this section.

* * * * *

(13) August 5, 1991, for products subject to paragraph (a)(26) of this section, except for those that contain live yeast cell derivative and a combination of hydrocortisone and pramoxine hydrochloride.

* * * * *

(37) September 25, 2003, for products subject to paragraph (a)(26)(xi) of this section.

Dated: August 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–21749 Filed 8–25–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) that appeared in the **Federal Register** of June 19, 2003 (68 FR 36744). FDA is correcting the amount of monocalcium phosphate in the formula for a free-choice, loose mineral Type C medicated feed containing lasalocid that was entered inaccurately. This correction is being made so the lasalocid regulations accurately reflect the approved formula.

DATES: This rule is effective June 19, 2003.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4567, e-mail: *ghaibel@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–15541, published on June 19, 2003 (68 FR 36744), the following correction is made:

§ 558.311 [Corrected]

■ On page 36745, in the first column, in the table in § 558.311 *Lasalocid* in paragraph (e)(4)(i), in the row for ''Monocalcium Phosphate'' the entry in the ''Percent'' column is corrected to read ''57.70''.

Dated: August 7, 2003.

David R. Newkirk,

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

[FR Doc. 03–21750 Filed 8–25–03; 8:45 am]

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