unchanged, FSIS will not require the binder name to appear in the name of the product; its appearance in the ingredients statement should be sufficient to inform consumers of its presence. For these reasons, FSIS is permitting the use of binders in ''Ham with Natural Juices'' products in an amount not exceeding 2 percent of product formulation, to prevent purging of the brine solution.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This final rule: (1) Preempts all state and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant and therefore has not been reviewed by OMB under Executive Order 12866.

The Administrator has made an initial determination that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The final rule permits the use of any one of the approved binders listed in 9 CFR 318.7(c)(4) in ''Ham with Natural Juices'' products. Manufacturers opting to use the approved binders in ''Ham with Natural Juices'' products will incur labeling expenses in revising the ingredients statements of their labels to show the presence of the approved binders. Decisions by individual manufacturers whether to use any one of the approved binders in ''Ham with Natural Juices'' products will be based on their conclusion that the benefits outweigh the implementation costs.

Paperwork Requirements

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this final rule in accordance with the Paperwork Reduction Act. This rule requires manufacturers opting to use one of the approved binders in ''Ham with Natural Juices'' products to revise their product labels. The labels will not be submitted to FSIS for approval because they are generically approved in accordance with 9 CFR 317.5. This information collection is approved under OMB number 0583–0094.

List of Subjects in 9 CFR Part 319

Food grades and standards, Food labeling.

For the reasons set out in the preamble, 9 CFR part 319 is amended as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

1. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

2. The first sentence of paragraph (d) of section 319.104 is revised to read as follows:

§ 319.104 Cured pork products.

* * * * *

(d) The binders provided in § 318.7(c)(4) of this subchapter for use in cured pork products may be used singly in those cured pork products labeled as ''Ham Water Added,'' ''Ham and Water Product-X% of Weight is Added Ingredients,'' and ''Ham with Natural Juices.'' * * *

Done at Washington, DC, on December 22, 1997.

Thomas J. Billy,

Administrator.

[FR Doc. 98–064 Filed 1–2–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Prednisolone Tablets

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 Lloyd, Inc. The supplemental NADA provides for an additional strength prednisolone tablet for dogs for use as an anti-inflammatory agent.

EFFECTIVE DATE: January 5, 1998.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1705.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 West Thomas Ave., Shenandoah, IA 51601, is the sponsor of NADA 140–921 that provides for use of prednisolone tablets for dogs as an anti-inflammatory agent. Lloyd, Inc., filed a supplemental NADA that provides for use of a 20 milligram (mg) prednisolone tablet in addition to the currently approved 5 mg tablet. The supplemental NADA is approved as of November 20, 1997, and the regulations are amended in § 520.1880(a) (21 CFR 520.1880(a)) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, the drug's name in § 520.1880(a) is amended to read ''prednisolone.''

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(d)(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 the 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.

§ 520.1880 [Amended]

2. Section 520.1880 *Prednisolone tablets* is amended in paragraph (a) by removing ''5 milligrams prednisolene'' and adding in its place ''5 or 20 milligrams prednisolone.''

Dated: December 17, 1997.

Robert C. Livingston,

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

[FR Doc. 98–74 Filed 1–2–98; 8:45 am]

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