DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 319

[Docket No. 96–040F]

RIN 0583–AC29

Use of Binders in ''Ham With Natural Juices'' Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat inspection regulations to permit the use of binders in ''Ham with Natural Juices'' products. FSIS currently permits the use of certain binders in cured pork products labeled ''Ham Water Added'' and ''Ham and Water Product-X% of Weight is Added Ingredients.'' FSIS is taking this action in response to a petition submitted by Hormel Foods Corporation, requesting the Agency to allow modified food starch (or ''food starch, modified'') to be used as a binder in ''Ham with Natural Juices'' products, in an amount not exceeding 2 percent of product formulation, to prevent purging of the brine solution, thereby retaining product moisture and enhancing texture.

EFFECTIVE DATE: March 6, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Post, Director, Labeling and Compounds Review Division, Office of Policy, Program Development, and Evaluation; (202) 205–0279.

SUPPLEMENTARY INFORMATION:

Background

On April 25, 1997, FSIS published a proposed rule in the **Federal Register** (62 FR 20130) to permit the use of modified food starch in ''Ham with Natural Juices'' products, in an amount not exceeding 2 percent of product formulation, to prevent purging of the brine solution. As noted in the proposal, FSIS does not permit the use of binders in ''Ham with Natural Juices'' products. FSIS has prohibited their use in ''Ham with Natural Juices'' products to prevent economic adulteration. FSIS believes that consumers consider ham products labeled ''Ham with Natural Juices'' to be premium products because they do not contain ''fillers,'' such as binders, and thus, are typically priced higher than the ''binders and water added'' ham products. Furthermore, in accordance with 9 CFR 319.104, ''Ham with Natural Juices'' products must meet a higher protein fat-free (PFF) value than other cured pork products, such as ''Ham Water Added'' and ''Ham and Water Product-X% of Weight is Added Ingredients,'' which reflects less added substances, including water.

The petitioner has developed a new process for producing its ''Ham with Natural Juices'' product in response to what they view as consumer demand for an improved ham product. The new process includes the use of modified food starch, which is currently prohibited in a ''Ham with Natural Juices'' product. According to the petitioner, its new ''Ham with Natural Juices'' process requires the use of modified food starch in order to enhance the characteristics of texture and, more importantly, moisture retention that consumers associate with the product.

Comments

FSIS received 9 comments during the public comment period that ended June 9, 1997. Six were from food companies and three were from trade associations. Six commenters expressed support for the proposal while three commenters opposed it.

Commenters in favor of the proposal generally stated that they believe it will allow the manufacture of products that meet the needs of consumers and enhance their satisfaction with ''Ham with Natural Juices'' products. They agreed with the petitioner that a ''Ham with Natural Juices'' product which contains a binder can be made to meet the PFF requirements for ''Ham with Natural Juices'' products without significantly changing the nutrient content of the product.

Commenters opposed to the proposal, however, felt strongly that, if implemented, it will compromise the quality of ''Ham with Natural Juices'' products and that the addition of modified food starch into the product will significantly change its expected characteristics. One commenter stated that the modified food starch will artificially retain moisture. As a result, the juices in the product will no longer be ''natural juices.'' The commenter pointed out that the product thus created is altered from the traditional product. Further, because the new brine binding technology as described in the proposal does not indicate whether the product is minimally processed or maintained in a natural state, the product does not meet the criteria for the term ''natural.'' In this commenter's opinion, the new product deviates from the current product identity expectation and does *not*, in fact, meet the consumer's expectations.

Another commenter expressed similar views. This commenter stated that, under natural conditions, a muscle will hold only a certain amount of moisture. The commenter further stated that, if this level is not acceptable to the petitioner and it feels it needs to alter the natural process by adding a binder, then the product should be labeled accordingly; however, the entire category of ''Ham with Natural Juices'' products should not be modified to permit the use of binders.

One commenter felt that the justification supplied for the addition of binders to ''Ham with Natural Juices'' products (to prevent purging of the brine solution) is weak. This commenter stated that properly processed ''Ham with Natural Juices'' products will have little, if any, purge.

The Final Rule

After reviewing the comments received, the Agency has concluded that ''Ham with Natural Juices'' remains an acceptable product identity. FSIS agrees with the petitioners and comments in favor of the proposal that ''Ham with Natural Juices'' products which contain a binder can, and must, meet the PFF requirements for ''Ham with Natural Juices'' products without significantly changing the nutrient content of the product. As indicated in the proposal, the petitioner has submitted technical data and other information demonstrating that the finished product does not fall below the minimum regulated PFF value with an acceptable yield loss, as illustrated by purged value differences over time. Because the product adheres to the minimum PFF value, even with the addition of modified food starch and other permitted binders, consumers will be receiving a ''Ham with Natural Juices'' product with essentially the same protein content and other nutrients as they do with a ''Ham with Natural Juices'' without binders. The concern of the commenters that the product no longer contains ''natural'' juices is diminished because of the adherence to the PFF value and the fact that no solutions are added that result in a cooked product that weighs more than its uncooked, cured green weight.

If a manufacturer decides to make a ''Ham with Natural Juices'' product that includes a binder, but which adheres to the PFF value for a ''Ham with Natural Juices'' product, it will have to be labeled accordingly. Modified food starch and the other permitted binders will have to appear in the ingredients statement to inform consumers of their presence. Because the PFF value for a ''Ham with Natural Juices'' product is

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]

BILLING CODE 4160–01–F