

response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to

the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. –Section 172.878 is amended in the table in paragraph (c) by adding an entry under the headings “Use” and “Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)” to read as follows:

§ 172.878 White mineral oil.

\* \* \* \* \*  
(c) \* \* \*

Use	Limitation (inclusive of all petroleum hydrocarbons that may be used in combination with white mineral oil)
* * *	* * * * *
16. As a dust control agent for rice.	ISO 100 oil viscosity (100 centistokes (cSt) at 100°F) applied at a level of no more than 0.08 percent by weight of the rice grain.

Dated: November 7, 1998.  
**L. Robert Lake,**  
*Director, Office of Policy, Planning, and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*  
[FR Doc. 98–31845 Filed 11–30–98; 8:45 am]  
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 98F–0063]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Natamycin (Pimaricin)

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a dry form of natamycin as an antimycotic in cheeses. This action is in response to a petition filed by Protein Technologies International, Inc.

DATES: This regulation is effective December 1, 1998; written objections and requests for a hearing by December 31, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JoAnn Ziyad, Center for Food Safety and Applied Nutrition (HFS–206), Food and

Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3116.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of February 11, 1998 (63 FR 6945), FDA announced that a food additive petition (FAP 8A4581) had been filed by Protein Technologies International, Checkerboard Sq., St. Louis, MO 63164. The petition proposes to amend the food additive regulations in § 172.155 *Natamycin (pimaricin)* (21 CFR 172.155) to provide for the safe use of a dry form of the food additive for use on the surfaces of cuts and slices of cheese to inhibit mold spoilage, in accordance with various standards of identity for cheeses that allow the use of antimycotics and anticaking agents.

–FDA received two comments from the food industry on the use of the dry mix of natamycin and cellulose on cheese to inhibit mold spoilage. Both comments favored the petitioned use of the additive. One comment listed several reasons for supporting the current petitioned use. They include possible extension of shelf life of shredded cheese, reduction of risks associated with antimycotic suspension spray application and minimal new technology investment by utilizing existing anticaking agent application technology. However, the other comment stated that “We realize that natamycin is permitted as a spray on the surface of cheese, but we are not comfortable with that method of application on grated cheese. We would like to test the efficacy of the method proposed in the cited petition.”

–FDA finds that the petitioner does not seek approval either for the use of the wet or dry application of the

additive on grated cheese. The petitioner requests that FDA amend the food additive regulation for natamycin (pimaricin) found in § 172.155 to allow for the use of a dry form of the food additive only on the surfaces of cuts and slices of cheese to inhibit mold spoilage, and this does not extend to use of the additive on grated or shredded cheese. Therefore, the comments on grated or shredded cheese are outside the scope of this rulemaking.

–Natamycin is currently approved in § 172.155 for use as an antimycotic agent on the surfaces of cuts and slices of cheese(s). Natamycin may be used on surfaces of cuts and slices of a cheese listed in 21 CFR part 133 only if the standards for such cheese provides for or the use of “safe and suitable” mold-inhibiting ingredients. The subject additive is defined in § 172.155 and may be applied by dipping or by spraying, using an aqueous solution containing 200 to 300 parts per million (ppm) of the additive. The proposed use is for the application of natamycin to cuts and slices of cheese as a dry mixture with safe and suitable anticaking agents, such as cellulose.

–FDA has evaluated the data in the petition and other relevant material. As part of its review, FDA evaluated data on the technical effect of the additive, its stability, and the change in exposure resulting from the use of a dry mixture of natamycin and cellulose anticaking agent. The petitioner provided data to establish that a level of up to 20 ppm natamycin in the finished product is needed to obtain the same antimycotic effect as from the liquid application.

–The petitioner, by measuring the antimycotic effect of a dry mixture of natamycin and cellulose on several

cheeses resulting in no more than 20 ppm of natamycin in these cheeses, demonstrated that the additive will achieve its intended technical effect. The application of natamycin in dry form does not change the chemical composition of the additive, the uses in food, the use levels and, therefore, the dietary exposure to natamycin. Furthermore, the use of natamycin in the dry form does not result in any manufacturing changes that would affect the safety of the additive for this proposed use. The use of comparable levels of other safe and suitable anticaking agents, in addition to cellulose, would not change this conclusion. Therefore, the agency's safety evaluation of natamycin for the approved use in an aqueous application by dipping or spraying (47 FR 26823, June 22, 1982, as amended at 50 FR 49536, December 3, 1985) supports this proposed use of natamycin in dry form. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 172.155 should be amended.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

—The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8A4581 (63 FR 6945, February 11, 1998). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

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

Any person who will be adversely affected by this regulation may at any time on or before December 31, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the

regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 172

—Food additives, Reporting and recordkeeping requirements.

—Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Foods and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

#### PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

—1. The authority citation for 21 CFR part 172 continues to read as follows:

—**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

—2. Section 172.155 is amended by revising paragraph (c)(1) to read as follows:

#### § 172.155 Natamycin (pimaricin).

\* \* \* \* \*

(c) \* \* \*

(1) The additive may be applied as a dry mix containing the additive and safe and suitable anticaking agents, resulting in no more than 20 parts per million of the additive in the finished product, or by dipping or spraying, using an aqueous solution containing 200 to 300 parts per million of the additive.

\* \* \* \* \*

Dated: November 7, 1998.

**L. Robert Lake,**

*Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.*

[FR Doc. 98-31855 Filed 11-30-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 343

[Docket No. 77N-094A]

#### Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-The-Counter Human Use; Final Rule for Professional Labeling of Aspirin, Buffered Aspirin, and Aspirin in Combination With Antacid Drug Products; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of October 23, 1998 (63 FR 56802). The document provided for professional labeling for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic drug products containing aspirin, buffered aspirin, and aspirin in combination with an antacid. The document published with some inadvertent editorial errors. This document corrects those errors.

**EFFECTIVE DATE:** The regulation is effective October 25, 1999.

**FOR FURTHER INFORMATION CONTACT:** Ida I. Yoder, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 98-28519, appearing on page 56802, in the **Federal Register** of October 23, 1998, the following corrections are made:

1. On page 56809, in Table 5, in the second entry in the fourth column, “-3.9” is corrected to read “-39”.

2. On page 56810, in the third column, in the eighteenth line, “preoperative” is corrected to read “perioperative”.

3. On page 56812, in the first column, in the third paragraph, in the eighteenth line, “were” is corrected to read “was”.

#### § 343.80 [Corrected]

4. On page 56817, in § 343.80(a)(1), the last paragraph is corrected to read “REV: October 23, 1998”.