By the Federal Home Loan Bank Board.

John F. Ghizzoni,

Assistant Secretary.

[FR Doc. 88-7516 Filed 4-5-88; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-ASW-39; Amdt. 39-5887]

Airworthiness Directives; Hercules; Lenair Corporation; Smith Helicopters; and West Coast Fabrications; Model UH-1E, UH-1L, and TH-1L Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD) which requires repetitive inspections and imposes a maximum service life on certain rod end bearing assemblies in the flight control system on Model UH-1E, UH-1L, and TH-1L helicopters (certified by Hercules; Lenair Corporation; Smith Helicopters; and West Coast Fabrications). The AD is needed to preclude possible failure of the main rotor assembly which, in turn, could cause loss of the helcopter.

DATES: *Effective Date:* May 6, 1988.

Compliance: As indicated in body of the AD.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Henry, Helicopter Certification Branch, ASW-170, Federal Aviation Administration, Fort Worth, Texas 76193-0170, telephone (817) 624-5168.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations (FAR) to include an airworthiness directive requiring repetitive inspections of the rod end bearing assembly to check for cracks and establish a 600-hour service life on newly added parts on certain model UH-1E, UH-1L, and TH-1L helicopters (modified by Hercules; Lenair Corporation; Smith Helicopters; and West Coast Fabrications) was published in the **Federal Register** on December 23, 1987 (52 FR 48542). The proposal was prompted by a U.S. Army Aviation command message which reported a rod end bearing assembly on an AH-1 helicopter failed at 790 hours' time in service due to a crack which originated near a staking mark on the bearing housing. Also, the FAA was informed by message from the Pensacola Naval Aviation Depot that the U.S. Navy would require a review of service life history on the P/N 204-076-428 rod end bearing assemblies for all Model UH-1E, UH-1L, TH-1L, and HH-1k helicopters. Bearings with 600 or more hours' time in service are to be replaced when serviceable parts become available. Failure of the rod end bearing assembly could result in possible failure of the main rotor assembly and loss of the helicopter.

Since this condition is likely to exist on FAA certificated UH-1E, UH-1L, and TH-1L helicopters of the same military design, an AD is being issued which requires repetitive inspections of the rod end bearing assembly to check for cracks and establishes a 600-hour service life on newly added parts.

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were received. Accordingly, the proposal is adopted without change.

The FAA has determined that this regulation involves approximately 19 aircraft with an estimated cost of approximately $16,500 per aircraft. Costs would not exceed $26,000 for any one operator. Therefore, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) will not have a significant impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained from the Regional Rules Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the FAR as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new AD:

Hercules; Lenair Corporation; Smith Helicopters; and West Coast Fabrications; Applies to Models UH-1E, UH-1L, and TH-1L helicopters certified by Hercules; Lenair Corporation; Smith Helicopters, and West Coast Fabrications certified in any category that have P/N 204-076-428-1, -3, or -5 rod end bearing assemblies installed.

Compliance is required as indicated, unless already accomplished.

To detect possible cracks in the collective and cyclic rod end bearing assemblies, P/N 204-076-428-1, -3, or -5, installed on Models UH-1E, UH-1L, and TH-1L helicopters, accomplish the following:

(a) Prior to the next flight after the effective date of this AD and thereafter at intervals not to exceed 10 hours' time in service from the last inspection, visually inspect the rod end bearing assemblies for cracks. Perform the visual inspections by disconnecting the cyclic and collective control tube assemblies from the swashplate horns and the collective pitch control lever.

(b) Whenever the rod end bearing assemblies are removed for any reason, inspect for cracks using a fluorescent penetrant or equivalent method.

Note: Inspections specified by paragraphs (a) and (b) above are not required on rod end bearing assembly P/N 204-076-428-5 having documented time in service of less than 600 hours.

(c) If a crack is found during these inspections replace the rod end bearing with a serviceable part prior to further flight.

(d) Replace rod end bearing assemblies, P/N 204-076-428-1 or -3 within 11 calendar months from the effective date of this AD with rod end bearing assembly, P/N 204-076-428-5, having a documented known service life of less than 600 hours' time in service.

(e) Replace rod end bearing assembly P/N 204-076-428-5, not having a documented known service life, or those with greater than 600 hours' time in service, within 11 calendar months from the effective date of this AD with rod end bearing assembly P/N 204-076-428-5 having a documented service life of less than 600 hours' time in service.

(f) Retire from service rod end bearing assembly, P/N 204-076-428-5 at 600 hours' time in service or less after initial replacement described in paragraphs (d) and (e).

(g) An alternate method of compliance which provides an equivalent level of safety with this AD may be used when approved by the Manager, Helicopter Certification Branch, Federal Aviation Administration, Fort Worth, Texas, 76193-0170.

This amendment becomes effective May 6, 1988.

Issued in Fort Worth, Texas, on March 24, 1988.

L.B. Andriesen,

Acting Director, Southwest Region.

[FR Doc. 88-7497 Filed 4-5-88; 8:45 am]

BILLING CODE 4910-13-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Dkt. C-3223]

Great Earth International, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a Santa Ana, Calif.-based food supplements franchisor from making certain claims about the supplements' effectiveness. Respondent is also prohibited from using the name "Growth Hormone Releaser," "GHR," or any similar name unless it has substantiation that the product stimulates the body or pituitary gland to release significantly greater amounts of human growth hormone in users than in non-users.

DATE: Complaint and Order issued March 15, 1988.[1]

FOR FURTHER INFORMATION CONTACT: Janice Frankle, FTC/S–4631, Washington, DC 20580. (202) 326–3022.

SUPPLEMENTARY INFORMATION: On Tuesday, January 5, 1988, there was published in the **Federal Register**, 53 FR 141, a proposed consent agreement with analysis In the Matter of Great Earth International, Inc., a corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Advertising Falsely Or Misleadingly: § 13.10 Advertising falsely or misleadingly; § 13.170 Qualities or properties of product or service; § 13.170–52 Medicinal, therapeutic, healthful, etc.; § 13.170–70 Preventive or protective; § 13.170–74 Reducing, non-fattening, low-calorie, etc.; § 13.190 Results; § 13.205 Scientific or other relevant facts. Subpart—Corrective Actions And/Or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–10 Corrective advertising; § 13.533–45 Maintain records; § 13.533–45(a) Advertising substantiation; § 13.533–45(k) Records, in general; § 13.533–50 Maintain means of communication. Subpart—Misrepresenting Oneself And Goods—Goods: § 13.1590 Composition; § 13.1590–20 Federal Trade Commission Act; § 13.1710 Qualities or properties; § 13.1730 Results; § 13.1740 Scientific or other relevant facts.

List of Subjects in 16 CFR Part 13

Food Supplements, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45, 52)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 88–7467 Filed 4–5–88; 8:45 am]

BILLING CODE 6750–01–M

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue NW., Washington, DC 20580.

16 CFR Part 13

[Dkt. C-3224]

Supermarket Development Corp., et al.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order requires, among other things, Furr's, a wholly owned subsidiary of Supermarket Development Corporation, to divest supermarkets in 12 towns and cities in Texas and New Mexico, to obtain prior Commission approval for future acquisitions by Furr's of grocery store located in the El Paso division, and to hold separate the El Paso division until the required divestitures are completed.

DATE: Complaint and Order issued March 17, 1988.[1]

FOR FURTHER INFORMATION CONTACT: Joan Greenbaum, FTC/S–3302, Washington, DC 20580. (202) 326–2629.

SUPPLEMENTARY INFORMATION: On Thursday, August 20, 1987, there was published in the **Federal Register**, 52 FR 31412, a proposed consent agreement with analysis In the Matter of Supermarket Development Corporation and SSI Associates, L.P., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of order.

Comments were filed and considered by the Commission. The Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart—Acquiring Corporate Stock Or Assets: § 13.5 Acquiring corporate stock or assets; § 13.5–20 Federal Trade Commission Act. Subpart—Corrective Actions And/Or Requirements: § 13.533 Corrective actions and/or requirements; § 13.533–45 Maintain records; § 13.533–45(k) Records, in general; § 13.533–50 Maintain means of communication.

List of Subjects in 16 CFR Part 13

Grocery Stores, Supermarkets, Trade practices.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; sec. 7, 38 Stat. 731, as amended; 15 U.S.C. 45, 18)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 88–7468 Filed 4–5–88; 8:45 am]

BILLING CODE 6750–01–M

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue NW., Washington, DC 20580.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 75G-0265]

Nisin Preparation; Affirmation of GRAS Status as a Direct Human Food Ingredient

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that nisin preparation produced from *Streptococcus lactis* Lancefield Group N is generally recognized as safe (GRAS) for use as an optional antimicrobial agent to inhibit the outgrowth of *Clostridium botulinum* spores and toxin formation in certain pasteurized cheese spreads. This action responds to a petition filed by Aplin and Barrett Ltd., requesting that nisin be affirmed as

GRAS for use as an antimicrobial preservative in food.

DATES: Effective April 6, 1988. The Director of the Office of the Federal Register approves the incorportion by reference of certain publications at 21 CFR 184.1538 in the introductory text of paragraph (b) and in paragraph (d) effective April 6, 1988.

ADDRESS: Background information on the environmental and economic effects and the references are on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

SUPPLEMENTARY INFORMATION:

I. Introduction

Under the procedures described in § 170.35 (21 CFR 170.35), Aplin and Barrett Ltd., Trowbridge, Wilts., England BA14 8HS submitted a petition (GRASP 5G0049) proposing affirmation that nisin is generally recognized as safe (GRAS) for use in food as an antimicrobial preservative. FDA published a notice of the filing of this petition in the **Federal Register** of Sepetember 17, 1975 (40 FR 42912), and gave interested persons an opportunity to submit comments to the Hearing Clerk (since renamed Dockets Management Branch) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857. FDA did not receive any comments in response to the notice.

On April 17, 1980, the petitioner limited its request for GRAS affirmation to the use of the nisin as an antimicrobial agent in certain pasteurized process cheese covered by 21 CFR 133.169 and 133.170 and in certain pasteurized process cheese spreads covered by 21 CFR 133.179 and 133.180. The petition was amended by the petitioner further on September 30, 1984, to request GRAS affirmation of nisin for use as an antimicrobial agent to inhibit the outgrowth of *Clostridium botulinum* (*C. botulinum*) spores and toxin formation in certain standardized pasteurized cheese spreads. Concurrently, the petitioner requested that the appropriate standards of identity for these cheese spreads be amended to permit the use of nisin. The cheese spreads affected are covered by the standards of identity listed in 21 CFR 133.175 *Pasteurized cheese spread;* 21 CFR 133.176 *Pasteurized cheese spread with fruits, vegetables, or meats;* 21 CFR 133.179 *Pasteurized process cheese spread;* and 21 CFR 133.180 *Pasteurized process cheese spread with fruits, vegetables, or meats.*

Published elsewhere in this issue of the **Federal Register** is a proposal to amend the standards of identity for these foods to provide for the use of nisin preparation as an optional antimicrobial agent.

The petition for GRAS affirmation includes data that show that nisin has been used experimentally outside of the United States as an antimicrobial preservative in a variety of foods, including cheeses and cheese products, since 1953. However, nisin has been used commercially outside of the United States only since 1960 (Refs. 1 and 2). Nisin has no history of common use in food in the United States. Based on these facts, the agency has concluded that nisin is not GRAS based on history of common use in food before 1958. However, the agency has determined that the petition meets the requirements of 21 CFR 170.30(b) for consideration of nisin as GRAS based on scientific procedures.

In evaluating this petition, as amended, the agency considered the following issues: (1) Identity and production of the ingredient; (2) proposed food uses; and (3) safety of the proposed food uses.

II. Data Summary and Evaluation

A. Identify and Production of the Ingredient

As early as 1928, scientists were aware that milk may contain a substance that can inhibit microbial growth. In 1947, Shattock and Mattick (Ref. 3) identified the microbial growth inhibitory substance as a product of lactice streptococci. They found that it is a strain of *Streptococcus lactis* (*S. lactis*) belonging to Lancefield Group N. Shattock and Mattick gave the microbial growth inhibitory substance the name "nisin."

Various strains of the organism *S. lactis* occur naturally in milk and are referred to as "cheese starter organisms." Commercial grade nisin is prepared from a pure culture fermentation of nonpathogenic strains of *S. lactis* Lancefield Group N with penicillin free, heat-treated sterilized nonfat milk digest. The product is then concenterated by a foaming process, extracted by salt precipition under acid conditions, and dried by a spray process. The product, as described in the petition, is a mixture or preparation, rather than a discrete entity, of *S. lactis* Lancefield Group N. Thus, the agency concludes that the appropriate name for the product is "nisin preparation" rather than "nisin," and the product hereinafter is called "nisin preparation" (NP).

The antimicrobial material in NP is "nisin," which, as described in the petition, is a group of closely related peptides that occur naturally and have an average molecular weight of 3,510. These peptides consist of the amino acids alanine, glycine, serine, aspartic acid, valine, histidine, lysine, leucine, isoleucine, methionine, proline, lanthionine, and beta-methyllanthionine.

Section 184.1538(c) contains specifications for NP (See Joint FAO/WHO Expert Committee on Food Additives, "Specifications for Identity and Purity of Some Antibiotics," FAO Nutrition Meeting Report Series, No. 45A (1969) (Ref. 4)) to assure that the character of NP remains consistent with the product evaluated in the petition.

B. The Proposed Food Uses of Nisin Preparation

The subject petition, as amended, seeks GRAS status for the use of NP sufficient to deliver 250 parts per million (ppm) of nisin as an inhibitor of the outgrowth of *C. botulinum* spores and toxin formation in pasteurized cheese spreads and pasteurized process cheese spreads covered by the standards of identity in 21 CFR 133.175, 133.176, 133.179, and 133.180. Although not mentioned in the petition, NP has been used outside of the United States as an antimicrobial preservative in various foods including canned pears, canned mushrooms, and canned tomatoes, as well as in process cheese products.

The standards of identity for the cheese spreads affected by the NP petition provide for a product with a relatively high moisture content (more than 44 percent but not more than 60 percent) and in which salt is an optional ingredient. In general, cheese spreads manufactured under these standards contain 50 to 54 percent moisture and 2 percent salt. In addition, pasteurized process cheese spreads may contain emulsifiers at levels of not more than 3 percent by the weight of the spread. Most contain about 2.5 percent emulsifier.

Under these conditions, the outgrowth of *C. botulinum* spores and resultant toxin formation is unlikely. However, unpublished studies in the petition (Refs. 5 and 6) show that at the higher moisture levels, the possibility exists that *C. botulinum* spore growth and toxin formation could occur when salt or emulsifier concentrations are lowered. These studies report that the minimum effective concentration of nisin against *C. botulinum* is greater than 100 ppm, but that quantities of nisin of 150 ppm

and 250 ppm are fully effective. In these studies (Refs. 5 and 6), using experimental formulations of process cheese spreads, the salt content was lowered, and the moisture content was increased above 55 percent. In addition, the phosphate emulsifier content varied from 2.5 percent to 1.3 percent.

In these studies, nisin prevented the outgrowth of *C. botulinum* spores and toxin formation at the level of (1) 12.5 ppm, when the salt content was reduced below 2 percent, and the moisture content (50 to 54 percent) and phosphate emulsifier content (2.5 percent) were normal; (2) 250 ppm, when the moisture content was above 55 percent, and the phosphate emulsifier and salt content were reduced below 2.5 percent and 2 percent, respectively; and (3) 250 ppm, when the moisture content was normal (50 to 54 percent), no salt was added, and the phosphate emulsifier content was reduced to 1.7 percent or less. Thus, the data from these studies demonstrate that 250 ppm nisin is effective in inhibiting the growth of *C. botulinum* spores and toxin formation in cheese spreads that have a high moisture (55 percent), low salt (below 2 percent), or low emulsifier (below 2.5 percent) content. For this reason, the agency concludes that the current good manufacturing practice level of NP for the requested use in the cheese spreads covered by the food standards is the quantity of NP that delivers a maximum of 250 ppm of nisin in the finished product.

Based upon the proposed uses of NP to provide a final concentration of 250 ppm of nisin in pasteurized cheese spreads and pasteurized process cheese spreads, the agency has calculated the estimated daily intake (EDI) for nisin to be 1 milligram per person per day (mg/person/day) (Ref. 7). This EDI corresponds to an intake of approximately 50 mg/person/day of NP, based on the use of NP containing 1×10^6 international units of nisin per gram (g) or approximately 2.5 percent nisin by weight (Ref. 6).

C. Safety of Nisin Preparation

The petition includes published and unpublished safety studies to support the safety of NP. The material tested in these studies was NP. Because of the design of these studies, however, many of the results were expressed in terms of the active ingredient nisin. The petition includes the following studies:

1. Acute Toxicity Studies

The acute oral dose (i.e., LD_{50}) for NP was found to be 6,950 milligrams per kilogram body weight (mg/kg body weight) for the mouse (Ref. 8). This dose corresponds to 174 mg nisin/kg body weight.

2. Subchronic Toxicity Studies

The petition contains data from two short-term studies. In one of the studies, rats were fed cheese containing NP equivalent to 1,204,000, 1,806,000, and 2,408,000 units of nisin/kg body weight for 12 weeks (Ref. 9). These levels correspond to 30.1, 45.2, and 60.2 mg nisin/kg body weight/day. In the other study, rats were fed diets containing NP at a level equivalent to 10,000 units of nisin per g of feed for 12 weeks (Ref. 10). This level corresponds to approximately 15 to 25 mg nisin/kg body weight/day. Neither study reported any difference between control and test animals in any of the parameters tested (growth, fertility, and gross/microscopic pathology).

3. Chronic Toxicity Study

The petition included a published chronic feeding study with a one-generation reproduction phase (Ref. 9) in which Wistar male and female rats of the F_0 (parental) generation were fed diets containing NP at levels equivalent to 33,300 units and 3,330,000 units of nisin per kg of food in the diet for 2 years. These levels correspond to .049 mg and 4.9 mg of nisin/kg body weight/day. The F_1 generation (offspring) male and female rats were fed the same diet as their parents for 40 weeks. No differences were reported between control and experimental animals of the F_0 generation in survival or reproductive performance. Organ weights and gross pathological and histological findings were normal in F_0 and F_1 males and females. Tests for hepatic, renal, and gastrointestinal function were normal in F_1 rats.

4. Reproduction Study

In support of the safety of NP the petitioner also submitted an unpublished three-generation reproductive study (Ref. 11) in which NP was administered orally to rats. The animals were fed a standard diet containing 0, 0.2, 1.0, or 5 percent NP for 26 weeks. These levels of NP correspond to 0.005, .025, or 0.125 percent of nisin or 13, 15, or 75 mg nisin/kg body weight/day. In the study, no difference was found between the test animals and controls in any of the test parameters measured (survival, growth, reproductive performance, and gross/microscopic pathology).

5. Sensitization Studies

The petition also included a study that shows that guinea pigs (Ref. 9) could not be sensitized to NP when NP was administered orally. No evidence of NP sensitization could be found in a comprehensive search by the agency of the scientific literature since 1980, suggesting that there are no published reports of nisin causing allergic reactions.

6. In Vitro Studies

An in vitro study using NP (Ref. 12) showed that nisin is degraded by pancreatin (an intestinal enzyme preparation), whereas certain therapeutic antibiotics that were tested are not, suggesting that nisin would not affect the intestinal flora. The author of the study hypothesized that nisin is rapidly hydrolyzed and inactivated shortly after it leaves the stomach.

7. Cross-resistance Studies

There is no evidence of cross resistance in important pathogenic organisms as a result of the use of NP. For example, studies in *Staphylococcus aureus, Escherichia coli,* and *Micrococcus pyogenes* var. *aureus* (Refs. 13 and 14) showed that exposure to NP did not result in any cross resistance that might affect the therapeutic use of other antibiotics.

Based on the chronic feeding study in rats (Ref. 9), the agency calculated an acceptable daily intake (ADI) for nisin of 2.9 mg/person/day (Ref. 15). This ADI exceeds the EDI (1 mg/person/day) of nisin from the proposed use of NP in pasteurized cheese spread (Ref. 7).

III. Conclusion on Proposed Uses of Nisin Preparation

Based on its review of the data submitted in the GRAS affirmation petition on the use of nisin preparation and of other relevant information, the agency concludes:

(1) The appropriate name for the ingredient is "nisin preparation" (NP) rather than "nisin."

(2) NP is adequately identified by the method of manufacture and specifications contained in the petition.

(3) NP sufficient to deliver 250 ppm nisin exhibits a functional effect in those standardized cheese spreads that contain high moisture, low salt, or low emulsifier content.

(4) The proposed use of NP is safe, based on the safety studies on NP. The ADI for nisin was calculated as 2.9 mg/person/day based on a chronic feeding study of NP. This level is more than two and one-half times larger than the EDI of 1 mg/person/day for nisin.

(5) NP is not eligible for GRAS status based on common use in food prior to January 1, 1958, because it had no

history of common use in food before that date.

(6) NP is GRAS based on scientific procedures. This conclusion is based on published safety data (including a chronic feeding study) which have been supplemented with unpublished data.

Therefore, the agency is affirming that NP is GRAS for use as an optional antimicrobial agent at a level sufficient to deliver 250 ppm nisin to inhibit the outgrowth of *C. botulinum* spores and toxin formation in the following pasteurized cheese spréads: pasteurized cheese spread under 21 CFR 133.175; pasteurized process cheese spread under 21 CFR 133.179; pasteurized cheese spread with fruits, vegetables, or meats under 21 CFR 133.176; and pasteurized process cheese spread with fruits, vegetables, or meats under 21 CFR 133.180.

IV. Environmental Effects

The agency has carefully considered the potential environmental effects of this action and 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 may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an abbreviated environmental assessment under 21 CFR 25.31a(b)(5).

V. Economic Effects

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this final rule would have on small entities including small businesses and has determined that the effect of this final rule is to provide for the use of NP as an optional antimicrobial ingredient to inhibit the outgrowth of *C. botulinum* spores and toxin formation in pasteurized cheese spreads. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA examined the economic effects of this rule. The agency has determined that it is not a major rule as defined by the Order.

The agency's findings of no economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Hawley, H. B., "Nisin In Food Technology," *Food Manufacturer*, pp. 1–11, August and September 1957.

2. Hawley, H. B., "Antibiotics In Food," *Laboratory Practice* pp. 659–653, September 1960.

3. Shattock, P.M.F., and Mattick, A.T.R., "Further Observation on an Inhibitory Substance (Nisin) from *Lactic Streptococci*," *The Lancet*, pp. 5–12, 1947.

4. Joint FAO/WHO Expert Committee on Food Additives, "Specifications for Identity and Purity of Some Antibiotics," FAO Nutrition Meetings Report Series, No. 45A, 1969.

5. Taylor, S.L., Somers, E.B., and Krueger, L.A., "Antibotulinal Effectiveness of Nisaplin in Process Cheese Spreads," (Unpublished report, 1982).

6. Taylor, S.L., Sommers, E.B., and Krueger, L.A., "Antibotulinal Effectiveness of Nisaplin in Reduced Sodium Process Cheese Spreads," (Unpublished report, 1984).

7. Memorandum of October 26, 1984, from John P. Modderman to John W. Gordon.

8. Hara, S., Yakazu, K., Nakakawaji, K., Takenchi, T., Kobayashi, T., Sata, M., Imai, Z., and Shibuya, T., "An Investigation of Toxicity of Nisin," *Tokyo Medical University Journal, 20:175–207, 1962.*

9. Frazer, A.C., Sharratt, M., and Hickman, J.R., "The Biological Effect of Food Additives—Nisin," *Journal of Science of Food and Agriculture*, 13:32–42, 1962. (Review article covers several studies).

10. Pesquera, T.I., "Nisin—Its Use, Estimation and Toxicology in Sterilized Milk," *Revista Espanola de Lecheria*, 59:16, 1966.

11. "Effect of Nisaplin on Reproductive Function of Multiple Generations in Rats," (Unpublished report, Huntington Research Centre, Cambridgeshire, England, 1984.

12. Heinemann, B., and Williams, R., "Inactivation of Nisin by Pancreatin," *Journal of Dairy Science*, 49:312–314, 1966.

13. Carlson, S., and Bauer H.M., "Nisin, eine antibakterieller/Wirkstoff aus *Streptococcus lactis* unter berucksichtingung des Resistenzproblems" *Archin fur Hygiene und Bakteriologie*, 141:6ff, 1975.

14. Szybalski, W., "Cross resistance of *Micrococcus pyogenes* var. *aureus* to Thirty-four Antimicrobial Drugs," *Antibiotics and Chemotherapy*, 3:1095–1102, 1953.

15. Memorandum of November 9, 1984, from Alfred N. Milbert to John W. Gordon.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

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, Part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201(s), 402, 409, 701, 52 Stat. 1046–1047 as amended, 1055–1056 as amended, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 342, 348, 371); 21 CFR 5.10, 5.61.

2. Part 184 is amended by adding new § 184.1538 to read as follows:

§ 184.1538 Nisin preparation.

(a) Nisin preparation is derived from pure culture fermentations of certain strains of *Streptococcus lactis* Lancefield Group N. Nisin preparation contains nisin (CAS Reg. No. 1414-45-5), a group of related peptides with antibiotic activity.

(b) The ingredient is a concentrate or dry material that meets the specifications that follow when it is tested as described in "Specifications for Identity and Purity of Some Antibiotics," World Health Organization, FAO Nutrition Meeting Report Series, No. 45A, 1969, which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408

(1) Nisin content, not less than 900 international units per milligram.

(2) Arsenic, not more than 1 part per million.

(3) Lead, not more than 2 parts per million.

(4) Zinc, not more than 25 parts per million.

(5) Copper, zinc plus copper not more than 50 parts per million.

(6) Total plate count, not more than 10 per gram.

(7) *Escherichia coli*, absent in 10 grams.

(8) *Salmonella*, absent in 10 grams.

(9) Coagulase positive staphylococci, absent in 10 grams.

(c) The ingredient is used as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter to inhibit the outgrowth of *Clostridium botulinum* spores and toxin formation in pasteurized cheese spreads and pasteurized process cheese spreads

listed in § 133.175; pasteurized cheese spread with fruits, vegetables, or meats as defined in § 133.176; pasteurized process cheese spread as defined in § 133.179; pasteurized process cheese spread with fruits, vegetables, or meats as defined in § 133.180 of this chapter.

(d) The ingredient is used at levels not to exceed good manufacturing practice in accordance with § 184.1(b)(1) of this chapter. The current good manufacturing practice level is the quantity of the ingredient that delivers a maximum of 250 parts per million of nisin in the finished product as determined by the British Standards Institution Methods, "Methods for the Estimation and Differentiation of Nisin in Processed Cheese," BS 4020 (1974), which is incorporated by reference. Copies are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, RM. 4–62, 5600 Fishers Lane, Rockville, MD 20857, or available for inspection at the Office of the Federal Register, 1100 L Street NW., Washington, DC 20408.

Dated: March 25, 1988.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 88–7459 Filed 4–5–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR PART 558

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

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that amended the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoffman-La Roche, Inc., providing for the safe and effective use of a Type C cattle feed manufactured from separately approved lasalocid sodium and oxytetracycline (monoalkyl trimethyl ammonium salt) Type A articles (52 FR 48095; December 18, 1987). The supplementary information in the final rule inadvertently omitted the approved level of 100-gram-per-pound oxytetracycline (monoalkyl trimethyl ammonium salt). This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jack C. Taylor, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5247.

SUPPLEMENTARY INFORMATION: In FR Doc 87–29036, appearing on page 48095 in the **Federal Register** of Friday, December 18, 1987 (52 FR 48095), in the second column under the heading "Supplementary Information" in the ninth line, the phrase "10– or 50–" should read "10–, 50–, or 100–".

Dated: March 31, 1988.

Richard A. Carnevale,

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

[FR Doc. 88–7525 Filed 4–5–88; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 800, 803, 807, 808, 809, 812, 813, 820, 860, 861, 864, 866, 876, 895, 1002, 1005, 1010, 1020, 1030, 1040, and 1050

[Docket No. 87N–0373]

Medical Device and Radiological Health Regulations; Editorial Amendments

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending certain of its regulations on medical device and radiological health to correct cross-references and typographical errors and to update the titles and mailing symbols of certain organizational units. This action will improve the accuracy and clarity of the regulations.

EFFECTIVE DATE: April 6, 1988.

FOR FURTHER INFORMATION CONTACT: T. Rada Proehl, Regulations Editorial Staff (HFC–222), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: FDA is revising certain of its regulations on medical devices and radiological health to correct cross-references and typographical errors, to update the titles and mailing symbols of certain organizational units, and to clarify the regulations. The affected regulations are 21 CFR 800.12(c) (the second time it appears), 803.33(b), 807.22(a), 807.35(b), 807.37 (a) and (b)(2), 807.90(a), 807.95(c)(1), 808.87(a), 809.5(a) (1), (2), (3), and (4) and (b), 812.2(e), 812.19, 812.20 (b)(9) and (d), 812.38(d), 813.20(a), 813.38 (b) and (c), 813.119(e)(2), 813.160, the introductory text of paragraph (a), 820.1(d), 820.3(f), 860.7(g)(4), 860.123(b)(1), 861.32 (b) and (c)(5), 864.9050(a), 864.9160(a), 866.5240(a), 866.5890(a), 876.5830(a), 895.21(d)(1), 1002.7, 1002.10, text of the introductory paragraph, 1002.20(a), the introductory text of paragraph (b), and (b)(5), 1002.31(c), 1002.41(a)(1), 1002.50, the introductory text of paragraph (a) and (b), 1002.51, 1005.11, 1005.25 (b) and (c), 1010.2 (c) and (d), 1010.3 (a)(1) and (2)(i), (b), and (c), 1010.4, the introductory text of paragraph (a), (b)(1)(viii), and (c) (1) and (3), 1010.5, the introductory text of paragraph (a), (b), (c)(12), and (e) (1) and (2), 1010.13, 1020.30 (c), (d), and (d)(3)(ii), 1020.32(a)(1), 1030.10(c) (4)(iv), (5)(iv), and (6)(iii), the introductory text of (c)(6)(iv), and (c)(6)(iv)(*d*), 1040.30(c)(1)(ii), and 1050.10(d)(5).

Because these amendments are nonsubstantive, notice and public procedure and delayed effective date are unnecessary (5 U.S.C. 553 (b)(B) and (d)).

List of Subjects

21 CFR Part 800

Administrative practice and procedure, Medical devices, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 803

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 809

Labeling, Medical devices.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 813

Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 861

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