inspections are carried out by highly qualified sanitarians and require knowledge and skills beyond the capability of a casual observer.

Comment: One commenter suggested that the reporting of intestinal illness be mandatory.

Response: Current regulations (42 CFR 71.21(c)) require the reporting of diarrheal illness by the master of a ship carrying 13 or more passengers prior to entering a port under the control of the United States.

Comment: One commenter stated his organization does not believe that the publication of a 5-year median score is either constructive or accurate. For example, a ship which has maintained consistently high scores for many years but which may have had one low score as a result of a health incident or on account of a virus or an unusual operating condition will find itself some 30 months later being shown with a very low median score to no purpose. The use of the median in this instance would merely confuse the public's perception as to the health standard which has been historically maintained in the vessel. This confusion will last during the period of 6 months in which the particular low score will be reported. Another commenter expressed the belief that reporting of median scores from the "old" system and current scores from the "modified" system is not productive. Another commenter stated the proposed publication of the "5-year median" score would present problems. The commenter stated, first of all, as proposed it would include the median results of inspections for the years 1984–1989 during which two entirely different scoring systems were used. Vessels scored under the two different systems would lead to different final scores which in turn would affect the percentage of ships that met standards or not. While the publication of the latest inspection score is a statement of fact, which can be documented by the individual vessel inspection report, the 5-year median raises more questions than answers and could lead to false conclusions.

Another commenter suggested that even further confusion would be caused in the minds of the traveling public by the publication of median scores in addition to the most recent score achieved by a ship and suggested that no statistics should be included other than that score received by the vessel in its most recent examination. Another commenter believed the change would be confusing to the public if a company were to acquire a ship (through purchase of the individual asset or of a whole company) which had historically had problems in achieving acceptable scores and should the buyer immediately turn the operation around, it will find itself haunted for the next 2½ years by a historical record which is both negative and irrelevant.

Another commenter suggested during such a long period of time vessels change ownership and management which can affect the operation of the vessel. Also, the past record of median scores, whether good, moderate, or low does not have any bearing on the sanitation conditions of the vessel during time of inspection or in the future, nor to the incidence of illness as documented by CDC and industry studies. And, finally, one commenter recommended, if regular summary reports are to be continued, they include only (a) the name of the vessel, (b) the most recent inspection score, and (c) the date of the inspection. Alternatively, if a median score of past inspections is to be included, these should include past scores going back to March 1987 only, at which time the new *Operations Manual* and the inspection scoring system currently in use were adopted. Vessels that change hands should have only the inspection score of the last inspection listed, with past median scores added for subsequent inspections. This approach would be similar to that proposed for new vessels.

Response: After careful consideration of the issues raised by several commenters, the Department agrees there exists the potential for confusion that would be counter productive to the Department's intentions if a 5-year median score were published as proposed. The Department agrees that a 5-year median score may not be indicative of the cruise lines current operations. Changes of ownership of vessels, changes in management of vessels, and subsequent changes in on board practices may make a 5-year median a misleading indicator of current levels of sanitation. The Department does not wish to penalize a vessel which has a history of unsatisfactory ratings but, under new management, is now making a concentrated effort to improve the level of sanitation on board. Publication of a 5-year median score which included previous unsatisfactory ratings could potentially reduce the incentive for a vessel to maintain a high level of sanitation as the results of their efforts would take them years to show. Upon further review of the scores during the past 5 years, the Department agrees that only those sanitation inspections conducted since March 1987, at which time the inspection scoring system currently in use was adopted, will be used in calculating a median of scores. The Department will not routinely publish the 5-year median but will maintain a 5-year median of scores achieved by a vessel during routine periodic sanitation inspections which will be available upon written request. Therefore, regular summary reports will continue to be published and will include only the name of the vessel, the numerical score of the most recent inspection, and the date of inspection.

Dated: March 1, 1989.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 89-5278 Filed 3-7-89; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 88N-0286]

Ray Batchelor Livestock; Withdrawal of Approval of Applications for Animal Feeds Bearing or Containing a New Animal Drug

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA), is withdrawing approval of all applications held by Ray Batchelor Livestock for animal feeds bearing or containing new animal drugs. This action is being taken because the firm failed to respond to a notice of opportunity for hearing proposing to withdraw approval of the applications.

EFFECTIVE DATE: March 20, 1989.

FOR FURTHER INFORMATION CONTACT: Philip J. Frappaolo, Center for Veterinary Medicine (HFV-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4940.

SUPPLEMENTARY INFORMATION: In the Federal Register of September 29, 1988 (53 FR 38074), CVM provided a notice of opportunity for a hearing on a proposal to withdraw approval of all the applications held by Ray Batchelor Livestock, P.O. Box 306, Enfield, NC 27823, for the manufacture of animal feeds bearing or containing new animal drugs (medicated feed applications).

Ray Batchelor Livestock holds the following medicated feed applications:

1. F110–725 for medicated feeds containing lincomycin for swine use; approved July 12, 1977.

2. F110–785 for medicated feeds containing melengestrol acetate for cattle use; approved July 15, 1977.

3. F111–150 for medicated feeds containing carbadox for swine use; approved September 2, 1977.

4. F111–176 for medicated feeds containing carbadox and pyrantel tartrate for swine use; approved September 9, 1977.

5. G128–373 for medicated feeds containing lincomycin for swine use; approved June 2, 1981.

The notice of opportunity for hearing stated that CVM was proposing to issue an order under section 512(m)(4)(B)(i) and (ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)(4)(B)(i) and (ii) withdrawing approval of the listed applications, and all amendments and supplements thereto, on the grounds that the applicant had refused to permit access to required records, and that new information, evaluated together with the evidence available when the applications were approved, showed that the methods used in, or the facilities and controls used for, the manufacturing, processing, and packing of such animal feeds were inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from FDA specifying the matters complained of. The firm was provided until October 31, 1988, to file a written appearance requesting a hearing (53 FR 38074 and 38075). Ray Batchelor Livestock failed to file such an appearance.

Under 21 CFR 514.200 *Contents of notice of opportunity for hearing*, the failure of the sponsor to file a written appearance in answer to a notice of opportunity for hearing constitutes a waiver of the right to a hearing and is grounds for CVM to summarily enter a final order withdrawing approval of the applications.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345–347 (21 U.S.C. 360(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval applications* (21 CFR 514.115), notice is given that approval of F110–725, F110–785, F111–150, F111–176, and G128–373 and all amendments and supplements thereto is hereby withdrawn, effective March 20, 1989.

Dated: February 28, 1989.

Gerald B. Guest,

Director Center for Veterinary Medicine.

[FR Doc. 89–5274 Filed 3–7–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89F–0050]

Stork Friesland B.V.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Stork Friesland B.V. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a polymeric reaction product of poly(*N*-vinyl-*N*-methylamine), *N,N'*-bis-(3-aminopropyl)-ethylenediamine, 1,3-benzenedicarbonyl chloride and 1,3,5-benzenetricarbonyl chloride as a reverse osmosis membrane intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Appied Nutrition (HFF–335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 9B4128) has been filed by Stork Friesland B.V., c/o Suite 200, 1029 Vermont Avenue NW., Washington, DC 20005–3517, proposing that § 177.2550 Reverse osmosis membranes (21 CFR 177.2550) be amended to provide for the safe use of a polymeric reaction product of poly(*N*-vinyl-*N*-methylamine), *N,N'*-bis-(3-aminopropyl)-ethylenediamine, 1,3-benzenedicarbonyl chloride and 1,3,5-benzenetricarbonyl chloride as a reverse osmosis membrane intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: February 27, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–5352 Filed 3–7–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86G–0122]

Diamond Crystal Salt Co.; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice of a petition requesting that the agency affirm that the use of *d*-α- and *dl*-α-tocopherols as inhibitors of nitrosamine formation in dry-cured bacon is generally recognized as safe (GRAS).

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, 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: In the Federal Register of April 10, 1986 (51 FR 12395), FDA published a notice that a petition (GRASP 6G0313) had been filed by Diamond Crystal Salt Co., St. Clair, MI 48079–1999. This petition asked that the agency affirm that the use of *d*-α- and *dl*-α- tocopherols as inhibitors of nitrosamine formation in dry-cured bacon is GRAS.

On August 19, 1986, FDA asked the firm for additional data to support the petition. This data has never been submitted to the agency.

On September 9, 1988, the agency contacted the firm by telephone to determine the firm's plans for the petition. The firm advised the agency that it intended to withdraw the petition and would send a letter requesting the withdrawal. However, 30 days later the agency had not received a letter from the firm asking that its petition be withdrawn.

Consequently, on October 18, 1988, FDA wrote the firm and advised it that because of the firm's lack of action in response to the communications between the agency and the firm, FDA was going to publish a notice in the Federal Register advising that it considered the petition to be withdrawn. More than 60 days have passed since that letter was sent, and the company has not voiced any objection to the projected course of action. Therefore, the agency is announcing that it considers this petition to be withdrawn by the firm in accordance with 21 CFR 171.7(b).

Dated: February 23, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–5276 Filed 3–7–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89M-0002]

Sola/Barnes-Hind; Premarket Approval of Polycon® HDK (Silafocon B) Gas Permeable Contact Lens for Extended Wear (Clear and Tinted)

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the supplemental application by Sola/Barnes-Hind, Sunnyvale, CA, for premarket approval, under the Medical Device Amendments of 1976, of the spherical POLYCON® HDK (silafocon B) Gas Permeable Contact Lens for Extended Wear (clear and tinted). After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of December 21, 1988, of the approval of the application.

DATE: Petitions for administrative review by April 7, 1989.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7940.

SUPPLEMENTARY INFORMATION: On May 27, 1988, Sola/Barnes-Hind, Sunnyvale, CA 94086-5200, submitted to CDRH a supplemental application for premarket approval of the POLYCON® HDK (silafocon B) Gas Preamble Contact Lens for Extended Wear (clear and tinted). The spherical lens is indicated for extended wear from 1 to 7 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The lens may be worn by persons who exhibit astigmatism of 4.00 diopters (D) or less that does not interfere with visual acuity. The spherical lens ranges in powers from −10.00 D to +10.00 D and is to be disinfected using the chemical lens care system recommended in the approved labeling. The blue tinted lens contains the color additive D & C Green No. 6 in accordance with the color additive listing provisions of 21 CFR 74.3206.

On October 20, 1988, the Ophthalmic Devices Panel, and FDA advisory committee, reviewed and recommended approval of the supplemental application. On December 21, 1988, CDRH approved the supplemental application by a letter to the applicant from the Acting Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ-460), address above. The labeling of the POLYCON® HDK (silafocon B) Gas Permeable Contact Lens for Extended Wear (clear and tinted) states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only.

Opportunity for Administrative Review

Section 515(d)(3) of the Act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the Act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before April 7, 1989, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: March 1, 1989.

Walter E. Gundaker,

Acting Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 89-5275 Filed 3-7-89; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service

Human Immunodeficiency Virus Services Planning Program Grants

AGENCY: Health Resources and Services Administration, PHS, DHHS.

ACTION: Notice of availability of funds.

SUMMARY: The Bureau of Maternal and Child Health and Resources Development (BMCHRD), Health Resources and Services Administration (HRSA), announces that Fiscal Year (FY) 1989 funds are available for Human Immunodeficiency Virus (HIV) Services Planning Program Grants to cities and States not affected by the Acquired Immune Deficiency Syndrome (AIDS) epidemic to the same extent as high incidence cities. All public and private entities are eligible to apply, including State and local Governments and nonprofit and for profit organizations capable of developing coordinated plans for services for persons with AIDS within designated cities and States. These entities must be able to consolidate the information received from governments, service providers, community coalitions, and community-based organizations into a comprehensive plan for a system-of-care. For statewide planning, entities must be able to document how they will utilize the information received from major cities within the State to reflect a cooperative statewide plan for services.

Eligible jurisdictions are determined based on the number of AIDS cases reported by the Centers for Disease Control as of September 12, 1988. Grant