NADA No.	Sponsor	Product name
100-090	Quality Plus Essar Corp.	Trisul. Sulfamethazine sodium. Sulfathiazole sodium. Sulfamerazine sodium. Sodium hydroxide. Sodium chloride. Sodium bicarbonate. Potassium chloride. Magnesium sulfate.
100-097	Quality Plus Essar Corp.	Sulfa-Urea Boluses. Sulfathiazole. Sulfamethazine. Urea.
100-181	Quality Plus Essar Corp.	Med-A-Sul. Sodium sulfathiazole. Sodium arsanilate anhydrous. Vitamin A (as palmitate). Vitamin D_3. Menadione sodium bisulfite. Calcium pantothenate. Niacin. Riboflavin. Thiamine hydrochloride. Ethylenediamine dihydroiodide. Potassium acetate. Sodium acetate. Sodium chloride. Potassium chloride. Magnesium sulfate. Calcium lactate.

IV. References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated October 2, 1984, from R. G. Gresham, International Multifood Corp., to Charles E. Haines, CVM.

2. Letter dated December 27, 1984, from Charles E. Haines, CVM, to R. G. Gresham, International Multifoods Corp.

3. Letter dated January 15, 1975, from R. E. Broyles, Ralston Purina Co., to Bureau of Veterinary Medicine (now CVM).

4. Letter dated April 23, 1975, from Adriano R. Gabuten, Bureau of Veterinary Medicine (now CVM), to R. E. Broyles, Ralston Purina Co.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 State. 343-351 (21 U.S.C. 360b)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Veterinary Medicine (21 CFR 5.84).

Dated: May 12, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89-12152 Filed 5-19-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0132]

Plascon-Gary, Inc.; Revocation of U.S. License No. 1020

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1020) and the product license issued to Plascon-Gary, Inc., for the manufacture of Source Plasma. In a letter received by the agency on March 1, 1989, the firm requested that its establishment and product licenses be revoked and thereby waived an opportunity for a hearing.

DATE: The revocation of the establishment and proudct licenses was effective March 17, 1989.

FOR FURTHER INFORMATION CONTACT: Andrea Chamblee, Center for Biologics Evaluation and Research (HFB-130), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-295-8188.

SUPPLEMENTARY INFORMATION: FDA has revoked the establishment license (U.S. License No. 1020) and the product license issued to Plascon-Gary, Inc., for the manufacture of Source Plasma. Plascon-Gary, Inc., was operating and doing business at the Broadway Plasma Center, 5150 Broadway, Gary, IN. The mailing address of Plascon-Gary, Inc., is 3764 North Illinois St., Indianapolis IN 46208.

On December 14, 1988, through January 4, 1989, FDA inspected Plascon-Gary, Inc. This inspection revealed serious deviations from the applicable biologics regulations and the firm's standard operating procedures. These deviations included, but were not limited to, the following: (1) Failure to determine plasma protein values due to the lack of a functioning refractometer, although plasma protein values were entered in the donor record files (21 CFR 640.63(c)(5)); (2) failure to maintain whole blood at proper storage temperatures in that whole blood was centrifuged at temperatures of −2 °C or lower (21 CFR 640.4(i)); (3) failure to maintain the sterility of the transfer sets used in processing in that plasma pooling technicians were observed on numerous occasions to touch the set spike prior to insertion into the blood bags (21 CFR 640.68(a)); (4) failure to assure that a qualified, licensed physician was on the premises during operating hours, in that after 12 m. on Tuesdays, Wednesday, Fridays, and Saturday, during which time the firm was open for donations,the physician was not available (21 CFR 640.62); (5) failure to store supplies in a safe and sanitary manner in that the ceiling leaked in several places, including in the supply storage area (21 CFR 606.65); (6) failure to restrict the use of blood collected from a donor whose blood is known to be repeatedly reactive for antibody to human immunodeficiency virus in that at least five such units of Source Plasma were shipped for further manufacture into injectable products (21 CFR 610.45(c)); and (7) failure to maintain and have available to personnel an up-to-date record of all unsuitable donors in that a donor deferral list was only available when the assistant manager was at the firm (21 CFR 606.160(e)); and (8) the list was not updated to include unsuitable donors since May 1987 (21 CFR 6060.160(e)).

FDA's investigation revealed that Plascon-Gary, Inc., was operating in significant noncompliance with the Federal standards designed to assure the safety, purity, and potency of plasma as well as the standards for donor protection which are intended to assure a continuous and health donor population. The investigation indicated that the individuals serving in supervisory positions at Plascon-Gary, Inc., did not adequately demonstrate their ability to operate the establishment in a manner that assures compliance with applicable regulations and the approved standard operating procedures for the firm.

Because these deviations represented a significant danger to health, FDA suspended the establishment license (U.S. License No. 1020) on January 19, 1989.

In a letter received by the agency on March 1, 1989 (dated February 17, 1989), Plascon-Gary, Inc., requested that its establishment and product licenses be revoked and thereby waived an opportunity for a hearing. The agency granted the licensee's request by letter to the firm dated March 17, 1989, issued under 21 CFR 601.5(a), which revoked the establishment license (U.S. License No. 1020) and the product license for the manufacture of Source Plasma issued to Plascon-Gary, Inc. FDA has placed copies of the letters dated January 19, February 17, and March 17, 1989, on file under the docket number found in brackets in the heading of this notice in

the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Accordingly, under 21 CFR 12.38 and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegatged under 21 CFR 5.68, the establishment license (U.S. License No. 1020) and the product license issued to Plascon-Gary, Inc., for the manufacture of Source Plasma were revoked effective March 17, 1989.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: May 11, 1989.

Gerald V. Quinnan, Jr.,

Deputy Director, Center for Biologics Evaluation and Research.

[FR Doc. 89–12153 Filed 5–19–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89F–0121]

Musashino Chemical Laboratory, Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Musashino Chemical Laboratory, Ltd. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of DL-alanine as a flavor enhancer for sweeteners in pickling mixtures.

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: 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 8A4106) has been filed by Musashino Chemical Laboratory, Ltd., 1–1 Kyobashi 1-Chome, Chuo-Ku, Tokyo 104, Japan, proposing that the food additive regulations be amended to provide for the safe use of DL-alanine as a flavor enhancer for sweeteners in pickling mixtures.

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: May 8, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89–12107 Filed 5–19–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89M–0154]

Zimmer USA; Premarket Approval of Biological Ingrowth Anatomic Stem (BIAS™) Fiber Metal Total Hip Stem

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Zimmer USA, Warsaw, IN, for premarket approval under the Medical Device Amendments of 1976, of the Biological Ingrowth Anatomic Stem (BIAS™) Fiber Metal Total Hip Stem. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of January 31, 1989, of the approval of the application.

DATE: Petitions for administrative review by June 21, 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: Thomas J. Callahan, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7156.

SUPPLEMENTARY INFORMATION: On June 26, 1987, Zimmer USA, Warsaw, IN 46580–0708, submitted to CDRH an application for premarket approval of the Biological Ingrowth Anatomic Stem (BIAS™) Fiber Metal Total Hip Stem. The device is indicated for noncemented use in skeletally mature individuals undergoing primary surgery for rehabilitating hips damaged as a result of noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastropic variant. The (BIAS™) Total Hip Stem is indicated for use with a cemented ultrahigh molecular weight polyethylene (UHMWP) acetabular cup to comprise a total hip system. Such systems consist of a femoral component, or stem, that is placed in the intramedullary canal of the femur and an acetabular component cemented in place in the pelvis. Regulatory review of safety and effectiveness data for the cemented use of the BIAS™ Total Hip Stem is not required at this time, because use of the device with bone cement has been found to be substantially equivalent to a generic type of device marketed in interstate commerce prior to May 28, 1976 (see 21 CFR 888.3350).

On January 22, 1988, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On January 31, 1989, CDRH approved the 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 Thomas J. Callahan (HFZ–410), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (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 June 21, 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: May 10, 1989.

Walter E. Gundaker,

Acting Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 89–12158 Filed 5–19–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89M–0153]

Steridyne Laboratories, Inc.; Premarket Approval of DYNASOL®

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Steridyne Laboratories, Inc., Hollywood, CA, for premarket approval, under the Medical Device Amendments of 1976, of DYNASOL®. The device is to be manufactured under an agreement with Visioncare Associates, Los Angeles, CA, which has authorized Steridyne Laboratories, Inc., to incorporate information contained in its approved premarket approval applications for the Vis-sol Saline Spray and VISTA-SOL® Preservative-free Sterile Saline Solution. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 14, 1989, of the approval of the application.

DATE: Petitions for administrative review by June 21, 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 Administrtion, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7940.

SUPPLEMENTARY INFORMATION: On October 11, 1988, Steridyne Laboratories, Inc., Hollywood, CA 90068, submitted to CDRH an application for premarket approval of DYNASOL®. The device is a sterile preservative-free buffered physiological saline solution indicated for use in the rinsing, heat disinfection, and storage after heat disinfection of soft (hydrophilic) contact lenses. The application includes authorization from Visioncare Associates, Los Angeles, CA 90048, to incorporate information contained in its approved premarket approval applications for the Vis-sol Saline Spray and VISTA-SOL® Preservative-free Sterile Saline Solution.

On April 14, 1989, CDRH approved the 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.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (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 June 21, 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(d), 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: May 10, 1989.

Walter E. Gundaker,

Acting Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 89–12157 Filed 5–19–89; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 89M–0143]

Schneider (USA) Inc.; Premarket Approval of the Schneider MICROSOFTRAC™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Schneider (USA) Inc., Minneapolis, MN, for premarket approval, under the Medical Device Amendments of 1976, of the Schneider MICROSOFTRAC™ Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter. After reviewing the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of April 14, 1989, of the approval of the application.

DATE: Petitions for administrative review by June 21, 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