and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: Cargill Inc., Nutrena Feed Division, P.O. Box 5614, Minneapolis, MN 55440, is the sponsor of NADA 98–595, which provides for use of a tylosin Type A medicated article to make Type C cattle, chicken, and swine feeds. In its letter of June 30, 1992, Nutrena requested that FDA withdraw approval of NADA 98–595 because it no longer manufactures or distributes the product. The NADA, originally held by Walnut Grove Products, W. R. Grace & Co., was purchased by Nutrena, effective September 13, 1991.

Therefore, 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 of applications* (21 CFR 514.115), notice is given that approval of NADA 98–595 and all supplements and amendments thereto is hereby withdrawn, effective November 27, 1992.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) and 558.625(b)(28) to reflect its withdrawal of approval of this NADA.

Dated: November 6, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 92–27767 Filed 11–16–92; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0395]

Withdrawal of Approval of Combination Procaine Penicillin and Streptomycin or Dihydrostreptomycin Containing NADA's

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of nine new animal drug applications (NADA's) for combination procaine penicillin and streptomycin or dihydrostreptomycin containing drug products. Approval of the NADA's listed below are being withdrawn on the grounds that withdrawal has been requested by their respective sponsors.

EFFECTIVE DATE: Withdrawal of these approvals is effective June 1, 1993.

FOR FURTHER INFORMATION CONTACT: Mukund Parkhie,Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8758.

SUPPLEMENTARY INFORMATION: FDA has concluded, based upon an evaluation of effectiveness by the National Academy of Sciences/National Research Council Drug Efficacy Study Implementation Group, that there is a lack of substantial evidence that these drug products are effective for use as fixed combinations under the conditions prescribed, recommended, or suggested in the labeling. FDA informed the sponsors of this fact, and all sponsors requested voluntary withdrawal of approval of their applications. The NADA sponsors have also, by request, waived their opportunity for a hearing. The NADA's are identified as follows:

SPONSOR	DOSAGE FORM	DRUG INGREDIENTS	NADA NO.
Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	Injection	Procaine penicillin Dihydrostreptomycin sulfate	65–170
Solvay Animal Health, Inc., 1201 Northland Dr., Mendota Heights, MN 55120.	Injection	Procaine penicillin Dihydrostreptomycin sulfate	65–089
The Upjohn Co., Kalamazoo, MI 49001	Injection	Procaine penicillin Prednisolone Dihydrostreptomycin sulfate	65–098
Pfizer, Inc., 235 East 42d St., New York, NY 10017.	Injection	Procaine penicillin Dihydrostreptomycin sulfate	65–086
	Medicated Feed	Procaine penicillin Streptomycin sulfate	46–726
Schering-Plough Animal Health Corp., P.O. Box 529, Galloping Hill Rd., Kenilworth, NJ 07033.	Injection	Procaine penicillin Chlorpheniramine maleate Diphemanil methyl sulfate Dihydrostreptomycin sulfate	65–073
	Injection	Procaine penicillin Chlorpheniramine maleate Dexamethasone Dihydrostreptomycin sulfate	65–029
Merck Sharp & Dohme Research Labs., Division of Merck & Co., Inc., Rahway, NJ 07065.	Injection	Procaine penicillin Dihydrostreptomycin sulfate	65–028
	Medicated Feed	Procaine penicillin Streptomycin sulfate	46–981

Withdrawal of approval of these applications is effective June 1, 1993. Prior to that date, the agency will republish this notice and publish any final rules necessary to revoke drug approvals which are codified in 21 CFR part 500, effective June 1, 1993. At that time distribution from sponsor-owned facilities must cease. All manufacturing of the products will cease by March 1, 1993. The agency will exercise its enforcement discretion and will not take regulatory action based on lack of approval against the following finished dosage form product that are subject to any of the above-listed NADA's: (1) Products distributed from the sponsor-owned facilities on or before June 1, 1993, and used before their expiration dates; or (2) products that are imported from a foreign manufacturing facility and are pending entry into the United States on June 1, 1993, due to administrative delays that are not the responsibility of the sponsor.

Therefore, 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 of applications* (21 CFR 514.115), notice is given that approval of the NADA's listed above and all supplements and amendments thereto is hereby withdrawn, effective June 1, 1993.

Dated: November 5, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 92–27793 Filed 11–16–92; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N-0419]

Drug Export; Hepatitis C Virus Encoded Antigen (Recombinant c22-3, c200, and NS5) ORTHO™ HCV 3.0 Elisa Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ortho Diagnostic Systems Inc., has filed an application requesting approval for the export of the biological product Hepatitis C Virus Encoded Antigen (Recombinant c22-3, c200, and NS5) ORTHO™ HCV 3.0 Elisa Test System to Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and The United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Frederick W. Blumenschein, Center for Biologics Evaluation and Research (HFB-124), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8191.

SUPPLEMENTARY INFORMATION: The Drug Export Amendments Act of 1986 (Pub. L. 99-660) (section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382)) provides that FDA may approve applications for the export of biological products that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Ortho Diagnostic Systems Inc., Route 202, Raritan, NJ 08869, has filed an application requesting approval for the export of the biological product Hepatitis C Virus Encoded Antigen (Recombinant c22-3, c200, and NS5) ORTHO™ HCV 3.0 Elisa Test System to Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and The United Kingdom. The Hepatitis C Virus Encoded Antigen (Recombinant c22-3, c200, and NS5) ORTHO™ HCV 3.0 Elisa Test System is a qualitative, enzyme-linked, immunosorbent assay for the detection of antibody to hepatitis C virus (anti-HCV) in human serum or plasma. The application was received and filed in the Center for Biologics Evaluation and Research on September 23, 1992, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by November 27, 1992, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Biologics Evaluation and Research (21 CFR 5.44).

Dated: October 15, 1992.

Thomas S. Bozzo,

Director, Office of Compliance, Center for Biologics Evaluation and Research.

[FR Doc. 92-27768 Filed 11-16-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92F-0357]

BASF Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that BASF Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of a polysulfone resin consisting of 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-sulfonylbis[phenol] as an article or component of articles intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 1B4262) has been filed by BASF Corp., 1609 Biddle Ave., Wyandotte, MI 48192-3799. The petition proposes to amend the food additive regulations in § 177.1655 *Polysulfone resins* (21 CFR 177.1655) to provide for the safe use of a polysulfone resin consisting of 1,1'-sulfonylbis[4-chlorobenzene] polymer with 4,4'-(1-methylethylidene)bis[phenol] and 4,4'-sulfonylbis[phenol] as an article or component of articles 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: October 19, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-27795 Filed 11-16-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92E-0267]

Determination of Regulatory Review Period for Purposes of Patent Extension; Proleukin®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Proleukin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of

Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Proleukin®. Proleukin® (aldesleukin) is indicated for adult metastatic renal cell carcinoma. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Proleukin® (U.S. Patent No. Re. 33,653) from Cetus Oncology Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated July 20, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Proleukin® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Proleukin® is 2,955 days. Of this time, 1,708 days occurred during the testing phase of the regulatory review period, while 1,247 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* April 4, 1984. The applicant claims April 4, 1984, as the date the investigational new drug application (IND) became effective. FDA has verified the applicant's claim that the date the IND became effective was April 4, 1984.

2. *The date the application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act:* December 6, 1988. The applicant claims November 30, 1992, as the date the product license application (PLA 88–0660) was initially submitted. However, FDA records indicate that the PLA was received on December 6, 1988.

3. *The date the application was approved:* May 5, 1992. FDA has verified the applicant's claim that PLA 88–0660 was approved on May 5, 1992.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 3 years and 350 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before January 19, 1993, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before May 16, 1993, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92–27503 Filed 11–16–92; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Heart, Lung, and Blood Institute; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be closed in accordance with the provisions set forth in section 552b(c)(4) and 552(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Since it is necessary to schedule meetings well in advance, it is suggested that anyone planning to attend a meeting contact the Scientific Review Administrator to obtain meeting information and to confirm the exact date, time, and location.

Name of Panel: NHLBI SEP on Small Grant Program (RO3).

Scientific Review Administrator: Dr. Lynn M. Amende.

Telephone Number: 301–496–8818.

Dates of Meeting: November 30—December 1, 1992.

Place of Meeting: Bethesda Hyatt Regency, Bethesda, Maryland.

Time of Meeting: 10 p.m.

Reason for Closure: To review individual grant applications.

Name of Panel: NHLBI SEP on Health Outcomes of Psychosocial Interventions (Conference Phone Call).

Scientific Review Administrator: Dr. C. James Scheirer.

Telephone Number: 301–496–7363.