

consensus development among the participants in the National Laboratory Training Network as well as a similar forum for a national laboratory partnership.

b. Serve as a collaborator in the design, development, promotion, and evaluation of laboratory training materials.

c. Provide the interface between the educational and technical experts who develop and deliver laboratory training.

d. Compile and maintain national laboratory training resource guides and national training calendars.

e. Collaborate in the development and delivery of train-the-trainer workshops and seminars.

f. Collaborate in the evaluation of the overall effectiveness of the National Laboratory Training Network.

g. Collaborate in establishment of a Federal/State/Private Partnership to promote quality laboratory practice to achieve national health objectives.

#### Review and Evaluation Criteria

The application will be reviewed and evaluated on the following:

A. Extent to which the applicant understands the requirements, problems, objectives, complexities, and interactions required of this cooperative agreement;

B. Degree to which proposed objectives are clearly stated, realistic, measurable, time-phased, and related to the purpose of this project;

C. Degree to which the applicant provides evidence of an ability to carry out the proposed project and the extent to which the applicant institution documents demonstrated capability to achieve objectives similar to those of this project;

D. Extent to which professional personnel involved in this project are qualified, including evidence of past achievements appropriate to this project; and

E. Adequacy of plans for administering the project.

#### Executive Order 12372 Review

The application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number assigned to this program is 13.262.

#### Application Submission and Deadline

The Association of State and Territorial Public Health Laboratory Directors has been notified of the

availability of funds for this project and must submit an original and two copies of application form PHS 5161-1 to Henry S. Cassell, III, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., Room 300 (E-14), Atlanta, Georgia 30305 on or before April 15, 1989.

#### Where to Obtain Additional Information

If you are interested in obtaining additional information regarding this project, please refer to Announcement Number 997 and contact the following:  
*Business:* Terry Maricle, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 300 (E-14), Atlanta, Georgia 30305, Telephone: (404) 842-8575 or FTS 236-6575.

*Technical:* Carl H. Blank, Division of Training (G-25), Training and Laboratory Program Office, Centers for Disease Control, Atlanta, Georgia 30333, Telephone: (404) 639-3874 or FTS 236-3874.

Dated: March 7, 1989.

Robert L. Foster,

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

[FR Doc. 89-5907 Filed 3-14-89; 8:45 am]

BILLING CODE 4160-19-M

#### Food and Drug Administration

[Docket No. 88N-0335]

**Frank Veterinary Laboratories et al.; Drugs Containing Sulfamethazine, Sulfamethoxazole, Sulfamerazine, Sulfathiazole, Sulfapyridine, or Sulfanilamide for Oral, Injectable, Intramammary, or Intrauterine Use in Food-Producing Animals; Refusal to Approve NADA's**

**AGENCY:** Food and Drug Administration.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is issuing a final order refusing to approve certain new animal drug applications (NADA's) for drugs containing sulfamethazine, sulfamethoxazole, sulfamerazine, sulfathiazole, sulfapyridine, or sulfanilamide for oral, injectable, intramammary, or intrauterine use in food-producing animals. Each of the NADA's in question was listed in a notice of opportunity for a hearing, published in the Federal Register of November 15, 1988 (53 FR 46050), on a

proposal by CVM to refuse approval of the NADA's. This action is being taken because the sponsors either did not respond to the notice of opportunity for a hearing by December 15, 1988, as provided by the November 15, 1988, notice, or affirmatively elected not to avail themselves of an opportunity for a hearing on the refusal to approve the applications.

**DATES:** The refusals to approve certain NADA's are effective March 15, 1989; distribution of the products must cease May 15, 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:

##### I. Background Information

In the Federal Register of November 15, 1988 (53 FR 46050) (corrected December 12, 1988 (53 FR 49968), and December 23, 1988 (53 FR 51950)), CVM provided a notice of opportunity for a hearing on its proposal to refuse approval of 142 listed pending NADA's sponsored by 11 firms for products covered by § 510.450 (21 CFR 510.450). Section 510.450 provides for interim marketing of drugs that contain sulfamethazine, sulfamethoxazole, sulfamerazine, sulfathiazole, sulfapyridine, or sulfanilamide for oral, injectable, intramammary, or intrauterine use in food-producing animals and that are the subject of pending applications. The notice of opportunity for a hearing gave sponsors until December 15, 1988, to request a hearing on the proposed refusal.

##### II. List of Firms Having NADA's Subject to This Notice

1. Frank Veterinary Laboratories, 149 East Thompson, West St. Paul, MN 55118.
2. Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.
3. Illini Skylab, Inc., 1000 Macomb Rd., Rushville, IL 62681.
4. Salsbury Laboratories, Inc., 2000 Rockford Rd., Charles City, IA 50816-9989.
5. Norden Laboratories, Inc., 601 West Cornhusker Highway, Lincoln, NE 68521.

##### III. Affected NADA's and Grounds for Refusing Approval

All the pending NADA's for the sulfonamide-containing drugs affected by this notice are listed in the tables below, by the same drug groups and in

the same format used in the November 15, 1988, notice of opportunity for a hearing. The tables list each pending NADA, current sponsor, and product name. The grounds on which CVM provided an opportunity for a hearing on the proposed refusal to approve each listed NADA under section 512(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)) and FDA's regulations were provided in detail in the November 15, 1988, notice of opportunity for a hearing, which is being made a part of this notice by reference.

Frank Veterinary Laboratories, Veterinary Laboratories, Inc., and Illini Skylab, Inc., did not respond to the November 15, 1988, notice of opportunity for a hearing and CVM is refusing to approve those firms' NADA's. Salsbury Laboratories, Inc., by a letter dated December 14, 1988, stated that it elected not to request a hearing on the proposal to refuse approval of 11 of its pending NADA's, and CVM is refusing to approve those applications. Norden Laboratories, Inc., by a letter dated December 8, 1988, stated that it elected not to request a hearing on the proposal to refuse approval of two of its pending NADA's, and CVM is refusing to approve those applications. Therefore, under section 512(d)(1) of the act and § 514.200 (21 CFR 514.200), CVM is issuing this refusal to approve the following NADA's for the listed products, effective March 15, 1989. Because the NADA's are no longer pending, the products may no longer be marketed under § 510.450. To facilitate an orderly transition to the use of approved new animal drugs, however, distribution of the products is not required to cease until May 15, 1989.

NADA number	Sponsor	Product name
	<b>A. SULFAMETHAZINE ALONE</b>	
099-846	Salsbury Laboratories, Inc.	Sodium Sulfamethazine, 12.5% Drinking Water Solution
099-904	Veterinary Laboratories, Inc.	Sulfamethazine Boluses, 15 Grams
099-910	Veterinary Laboratories, Inc.	Sulfamethazine Sodium Solution 25%
099-998	Illini Skylab, Inc.....	Liquid
100-024	Veterinary Laboratories, Inc.	Vimethazine-25 Sulfamethazine Solution 25%
100-028	Illini Skylab, Inc.....	Vimethazine
100-071	Frank Veterinary Laboratories.	Frank Sodium Sulfamethazine Sorbitol Solution
100-126	Illini Skylab, Inc.....	Sulfamethazine Boluses

NADA number	Sponsor	Product name	NADA number	Sponsor	Product name
	<b>B. SULFATHIAZOLE ALONE OR IN COMBINATION WITH OTHER SULFA PRODUCTS</b>		099-861	Salsbury Laboratories, Inc.	Sulfanilamide Boluses
099-857	Salsbury Laboratories.	Sodium Sulfathiazole Soluble Powder	099-880	Veterinary Laboratories, Inc.	Tri-Metha Bolus
100-025	Veterinary Laboratories, Inc.	Tri-Sul 2MT Triple Sulfa Solution 24%	100-123	Illini Skylab, Inc.....	Sulfanilamide Sulfamethazine Triple Sulfa Bolus Sulfanilamide Sulfathiazole Sulfamethazine
		Sulfamethazine sodium		<b>G. NEW ANIMAL DRUGS CONTAINING SULFONAMIDES IN COMBINATION WITH NUTRIENTS OR OTHER DRUGS</b>	
		Sulfathiazole sodium	099-844	Salsbury Laboratories, Inc.	Hog & Cattle Sulfa
100-099	Illini Skylab, Inc.....	Sulfamerazine sodium			Sulfathiazole sodium sesquihydrate
100-117	Illini Skylab, Inc.....	Thiazole-Sodium Sulfathiazole sodium			Ethylenediamine dihydroiodide
	<b>C. SULFAQUINOXALINE ALONE OR IN COMBINATION WITH OTHER SULFA PRODUCTS</b>				Potassium chloride
099-867	Salsbury Laboratories, Inc.	Sulquin-40 Medicated Premix	099-856	Salsbury Laboratories, Inc.	Sodium chloride
100-029	Illini Skylab, Inc.....	Sulfaquinoxaline 20% Sulfa-Pol Liquid Concentrate			Sodium carbonate monohydrate
		Sulfamerazine			Hog & Cattle Sulfa with Vitamins and Electrolytes
		Sulfamethazine			Sulfathiazole sodium sesquihydrate
		Sulfaquinoxaline	099-862	Salsbury Laboratories, Inc.	Potassium chloride
	<b>D. SULFAMERAZINE</b>				Sodium chloride
None.					Sodium carbonate
	<b>E. SULFAPYRIDINE ALONE OR IN COMBINATION WITH OTHER SULFA PRODUCTS</b>				Vitamin A
099-986	Norden Laboratories, Inc.	Tri-Sulfa-G Sulfonamide Solution			Vitamin D <sub>3</sub>
		Sulfamethazine			SM-15 and SM-30 Sulfa Boluses with Electrolytes
		Sulfathiazole	099-863	Salsbury Laboratories, Inc.	Sulfamethazine Sodium
		Sulfapyridine			Potassium Chloride
100-070	Frank Veterinary Laboratories.	Frank Triple Sulfa Solution (INJ)			90-90-60 Sulfa Boluses with Electrolytes
		Sulfamethazine sodium			Sulfathiazole Sulfanilamide Sulfamethazine Calcium Chloride
		Sulfathiazole sodium	099-864	Salsbury Laboratories, Inc.	Magnesium Potassium Sodium
		Sulfamerazine sodium			T-M-P 80 Boluses with Electrolytes
100-072	Frank Veterinary Laboratories.	Frank Triple Sulfa Solution Oral 12%			Sulfathiazole Sulfamethazine Sulfapyridine Calcium Chloride
		Sulfamethazine sodium			Magnesium Potassium Sodium
		Sulfathiazole sodium	099-865	Salsbury Laboratories, Inc.	Triple Sulfa Boluses with Electrolyte 240 Grains & 480 Grains
		Sulfapyridine sodium			Sulfathiazole Sulfamethazine Sulfanilamide Calcium Chloride
	<b>F. SULFANILAMIDE ALONE OR IN COMBINATION WITH OTHER SULFA PRODUCTS</b>				
099-851	Salsbury Laboratories, Inc.	Sulfanilamide			

NADA number	Sponsor	Product name	NADA number	Sponsor	Product name
099-869	Veterinary Laboratories, Inc.	Magnesium Potassium Sodium Sulfa-Urea Bolus			
099-907	Veterinary Laboratories, Inc.	Urea Sulfanilamide Sulfathiazole Sulfathiazole Uterine Boluses Sulfathiazole Urea	100-122	Illini Skylab, Inc.	Sodium Trace amounts of cobalt, zinc, manganese, copper and iron Triple Sulfa Boluses with Electrolytes Sulfanilamide Sulfathiazole Sulfamethazine Potassium, calcium, magnesium, sodium, and trace amounts of cobalt, zinc, manganese, copper, and iron.
099-983	Illini Skylab, Inc.	Triple Sulfa with Electrolytes Sulfamethazine sodium Sulfathiazole sodium Sulfamerazine sodium Sodium Potassium Calcium Magnesium as chloride, carbonate, sulfate, and lactate, plus trace amounts of cobalt, zinc, copper, manganese, and iron			
099-988	Norden Laboratories, Inc.	Sulfamycin-S Powder Sulfamethazine Neomycin sulfate			
100-027	Illini Skylab, Inc.	Sulfa-Pol Plus TA Soluble Concentrate Sulfamethazine sodium Sulfamerazine sodium Sulfaquinoxaline sodium Thiamine hydrochloride Vitamin A palmitate water			
100-098	Illini Skylab, Inc.	Vi-Lite Sodium Sulfathiazole with Electrolytes Sodium sulfathiazole Sodium Potassium Calcium Magnesium Ethylenediamine dihydroiodide Vitamin A Vitamin D Iron occurring as chloride, carbonate, sulfate, phosphate, and lactate plus trace amounts of cobalt, zinc, copper, and manganese			
100-118	Illini Skylab, Inc.	Sulfamethazine Boluses with Electrolytes Sulfamethazine Sodium Potassium Calcium Magnesium			

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512, 82 Stat. 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: March 8, 1989.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 89-5995 Filed 3-14-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89F-0051]

#### Minnesota Mining and Manufacturing Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.  
ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Minnesota Mining and Manufacturing Co. has filed a petition proposing that the food additive regulations be amended to provide for additional vinylidene fluoride-hexafluoropropene copolymers as adjuvants in the production of olefin polymers.

**FOR FURTHER INFORMATION CONTACT:** Gillian Robert-Baldo, Center for Food Safety and Applied 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 9B4129) has been filed by Minnesota Mining and Manufacturing Co., 3M Center, St. Paul, MN 55144-1000, proposing that § 177.1520 *Olefin*

*polymers* (21 CFR 177.1520) be amended to provide for additional vinylidene fluoride-hexafluoropropene copolymers as adjuvants in the production of olefin polymers.

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: March 7, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-5939 Filed 3-14-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89F-0042]

#### Pfizer Central Research, Pfizer, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.  
ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Pfizer Central Research, Pfizer, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polydextrose in sweet sauces, toppings, and syrups.

**FOR FURTHER INFORMATION CONTACT:** John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street 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 9A4126) has been filed by Pfizer Central Research, Pfizer, Inc., 235 East 42nd St., New York, NY 10017, proposing that the food additive regulations be amended to provide for the safe use of polydextrose in sweet sauces, toppings, and syrups.

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 23, 1989.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 89-5940 Filed 3-14-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0092]

**Drug Export; Demerol® Hydrochloride (Meperidine Hydrochloride, USP)**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Sterling Drug Inc. has filed an application requesting approval for the export of the human drug Demerol® Hydrochloride (meperidine hydrochloride, USP) to Canada.

**ADDRESS:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:** Rudolf Apodaca, Division of Drug Labeling Compliance (HFD-310), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8063.

**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 drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. 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 Sterling Drug Inc., 90 Park Ave., New York, NY 10016, has filed an application requesting approval for the export of the drug Demerol® Hydrochloride

(meperidine hydrochloride, USP), to Canada. This product is used in the relief of moderate to severe pain in may medical, surgical, obstetrical, and dental situations. The application was received and filed in the Center for Drug Evaluation and Research on February 24, 1989, 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 March 27, 1989, 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, Pub. L. 99-660 (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 Drug Evaluation and Research (21 CFR 5.44).

Dated: March 6, 1989.

Daniel L. Michels,

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

[FR Doc. 89-5997 Filed 3-14-89; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 89N-0093]

**Drug Export; Hypaque® Meglumine 18%**

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Sterling Drug Inc. has filed an application requesting approval for the export of the human drug Hypaque® Meglumine 18% to Canada.

**ADDRESS:** Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and to the contact person identified below. Any further inquiries concerning the export of human drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

**FOR FURTHER INFORMATION CONTACT:**

Rudolf Apodaca, Division of Drug Labeling Compliance (HFD-310), Center for Drug Evaluation Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8063.

**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 drugs that are not currently approved in the United States. The approval process is governed by section 802(b) of the act. 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 Sterling Drug Inc., 90 Park Ave., New York, NY 10016, has filed an application requesting approval for the export of the drug Hypaque® Meglumine 18%, to Canada. This product is used as a radiopaque contrast media. The application was received and filed in the Center for Drug Evaluation and Research on February 24, 1989, 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.

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