

requesting the applicant to describe how these objectives will be reached; and certifications. Guidance for the content

of information requested in the Program Narrative is found in OMB Circulars A-102 and A-110.

*Respondents:* Applicants for ACF Discretionary Grant Programs.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application form .....	4,127	1	4	16,688

Estimated Total Annual Burden Hours: 16,688

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by FAX to (202) 260-3305 or by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identifiable by title.

In addition, requests may be made to the Reports Clearance Officer by sending an Internet e-mail message to [rkatson@cf.dhhs.gov](mailto:rkatson@cf.dhhs.gov). Electronic comments must be submitted as an ASCII file without special characters or encryption.

*Comments are invited on:* (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 1, 1996.

Roberta Katson,

*Director, Division of Information Resource Management Services.*

[FR Doc. 96-5828 Filed 3-11-96; 8:45 am]

BILLING CODE 4184-01-M

**Food and Drug Administration**

[Docket No. 96N-0055]

**Animal Drug Export; NUFLOR® (Florfenicol)**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Schering-Plough Animal Health, Schering-Plough Corp., has filed an application requesting approval for export of the animal drug NUFLOR® (florfenicol) injectable solution for cattle to Canada.

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

**FOR FURTHER INFORMATION CONTACT:** Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

**SUPPLEMENTARY INFORMATION:** The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs 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 Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed application number 4366 requesting approval for export of the animal drug NUFLOR® (florfenicol) injectable solution for cattle to Canada. The product is intended for intramuscular use in beef and non-lactating dairy cattle for treatment of bovine respiratory disease (shipping fever) associated with *Pasteurella hemolytica*, *P. multocida*, and *Haemophilus somnus*. The application was received and filed in the Center for Veterinary Medicine on February 15, 1996, 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 22, 1996, 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 Veterinary Medicine (21 CFR 5.44).

Dated: February 29, 1996.

Robert C. Livingston,

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

[FR Doc. 96-5747 Filed 3-11-96; 8:45 am]

BILLING CODE 4160-01-F

**[Docket No. 96N-0074]****Sperti Drug Products, Inc., et al.;  
Proposal To Withdraw Approval of 41  
New Drug Applications; Opportunity  
for Hearing****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.**SUMMARY:** The Food and Drug Administration (FDA) is offering an opportunity for a hearing on the agency's proposal to withdraw approval of 41 new drug applications (NDA's). The basis for the proposal is that the

sponsors have repeatedly failed to file required annual reports for these NDA's.

**DATES:** Written requests for a hearing are due by April 11, 1996; data and information in support of the hearing request are due by May 13, 1996.**ADDRESSES:** Requests for a hearing, supporting data, and other comments should be identified with Docket No. 96N-0074, and submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.**FOR FURTHER INFORMATION CONTACT:** Lola E. Batson, Center for Drug Evaluation

and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1038.

**SUPPLEMENTARY INFORMATION:** The holders of approved applications to market new drugs or antibiotic drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the NDA's listed in the table below have failed to submit the required annual reports, and have not responded to the agency's requests by certified mail for submission of the reports.

NDA no.	Drug	Applicant
4-749	Bio-Dyne Ointment	Sperti Drug Products, Inc.
8-532	Nicodrin Tablets	Gold Leaf Division, Ormont Drug and Chemical Co., Inc.
8-685	Puran Tablets	Pure Laboratories Inc.
8-891	Buffered Parasi-INH & INH 20 Tablets	Panray Division, Ormont Drug and Chemical Co., Inc.
10-353	Parasal-Potassium Tablets	Do.
11-902	Hematainer	Courtland Laboratories.
12-432	Meprobamate Tablets	Gyma Labs.
12-435	Nitrofurantoin Tablets	Do.
12-513	Pertranquil (Meprobamate) Tablets	Philadelphia Pharmaceutical and Cosmetic Co.
12-866	Meprobamate Tablets	Riverton Laboratories.
12-984	Secret Cream Deodorant	The Procter and Gamble Co.
14-344	Meprobamate Tablets	Bryant Pharmaceutical, Corp.
14-364	Meprobamate Tablets	Bates Laboratories, Inc.
14-365	Meprobamate Tablets	Philadelphia Laboratories, Inc.
14-367	Meprobamate Tablets	American Pharmaceutical Co. Inc.
14-368	Meprobamate Tablets	MK Laboratories, Inc.
14-509	Meprobamate Tablets	Chase Chemical Co.
14-511	Meprobamate Tablets	Davis-Edwards Pharmacal Corp.
14-600	Meprobamate Tablets	Vitamix Pharmaceuticals, Division of Philadelphia Pharmaceutical and Cosmetic Co.
14-769	Meprobamate Tablets	USV Pharmaceuticals.
14-862	Meprobamate Tablets	Gold Leaf Pharmacal Co., Inc.
15-081	Meprobamate Tablets	Kirkman Laboratories, Inc.
15-170	Meprobamate Tablets (FAS-CILE 400 and FAC-CILE 200).	Schlicksup Drug Co., Inc.
15-437	Meprobamate Tablets	Phoenix Laboratories, Inc.
16-051	Meprobamate Tablets	Lit Drug Co.
16-068	Meprobamate Tablets	Leeds-Dixon Laboratories, Inc.
16-107	Protran (Meprobamate) Tablets	Rand Laboratories, Inc.
16-254	Meprobamate Tablets	Modern Drugs, Inc.
16-731	Cuticura Medicated Soap	Purex.
17-240	Bio/Dopa (Levodopa) Capsules	Steri-Med.
17-343	Actin-N Nitrofurazone Topical Dressing	Sherwood Medical Co.
17-417	Westasept Topical Solution	West Chemical Products, Inc.
17-418	Wescohex Emulsion	Do.
17-419	Wescohex Topical Emulsion	The Vitarine Co., Inc.
17-423	Septisol Solution	Calgon Vestal Laboratories.
17-424	Septisol Foam	Do.
17-460	Septi-Soft Solution	Do.
17-540	Heparin Sodium Injection	Dell Laboratories.
17-544	Dancon Antidandruff Shampoo	The Wella Corp.
17-580	Dancon Antidandruff Shampoo	Do.
18-363	Hexascrub Sponge	Professional Disposables Inc., Division of Nice-Pak Products, Inc.

Therefore, notice is given to the holders of the NDA's listed in the table and to all other interested persons that

the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of

the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) withdrawing approval of the NDA's and

all amendments and supplements thereto on the ground that the applicants have failed to submit the reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before April 11, 1996, a written notice of participation and request for a hearing, and (2) on or before May 13, 1996, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: February 28, 1996.  
Janet Woodcock,  
*Director, Center for Drug Evaluation and Research.*  
[FR Doc. 96-5748 Filed 3-11-96; 8:45 am]  
BILLING CODE 4160-01-F

## Health Care Financing Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collection for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Payment Adjustment for Sole Community Hospitals; *Form No.:* HCFA-R-79; *Use:* Hospitals designated as "Sole Community Hospitals" that experience a five percent decrease in discharges in one cost reporting period, as compared to the previous period, due to unusual circumstances, beyond its control, may request an adjustment to its Medicare payment amount. *Frequency:* On

occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours Requested:* 160.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 4, 1996.  
Kathleen B. Larson,  
*Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.*

[FR Doc. 96-5772 Filed 3-11-96; 8:45 am]  
BILLING CODE 4120-03-P

## Health Resources and Services Administration

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129. The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title IV—The Maternal and Child Health Bureau (MCHB) proposes to collect aggregated data from 38 grantees and their 72 local service providers that are funded under Section 2671 of the Public Health Service Act (42 U.S.C. 300ff-71). Data will be collected from grantees and providers on the organizational structures, service delivery approaches, numbers and demographic characteristics of clients served, service utilization, and activities related to outreach, prevention, and education. The data collection strategy includes six tables that the grantees and their local