Social Security Administration

(Call Reports Clearance Officer on 301–594–5706 for copies of package)
Subject: Notice Regarding Substitution of Party Upon Death of Claimant-Reconsideration of Disability Cessation—Revision—(0960–0351)
Respondents: Individuals or households
Subject: Quarterly Statement of FAMIS Expenditures—Extension—(0960–0373)
Respondents: State or local governments
Subject: Quarterly Report of Recoveries of Overpayment (Aid to Families With Dependent Children)—Extension—(0960–0325)
Respondents: State or local governments
OMB Desk Officer: Judy A. McIntosh

Office of Human Development Services

(Call Reports Clearance Officer on 202–472–4415 for copies of package)
Subject: ACYF/NCCAN Program Advancement of the FY 1986 Availability of Funds for the Establishment and Operation of a National Information and Resource Clearinghouse—New
Respondents: Non-profit institutions
OMB Desk Officer: Judy A. McIntosh

Office of The Secretary

(Call Reports Clearance Officer on 202–245–6511 for copies of package)
Subject: Hill-Burton Community Service Assurance Report—Triennial III—Revision—(0990–0096)
Respondents: State or local governments; Non-profit institutions
OMB Desk Officer: Fay Iudicello.

Copies of the above information collection clearance packages can be obtained by calling the Reports Clearance Officer on the number shown above.

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, D.C. 20503. Attn: (name of OMB Desk Officer).

Dated: June 17, 1986.

Wallace O. Keene,

Acting Deputy Assistant Secretary for Management Analysis and Systems.

[FR Doc. 13940 Filed 6–19–86; 8:45 am]

BILLING CODE 4150–04–M

Centers for Disease Control

Project Grants for Sexually Transmitted Diseases Research, Demonstrations, and Public and Professional Education Availability of Funds for Fiscal Year 1986

Introduction

The Centers for Disease Control (CDC) announces the availability of funds for Fiscal Year 1986 for Project Grants for Sexually Transmitted Diseases (STD) Research Demonstrations, and Public Information and Education, and Professional Education, Training, and Clinical Skills Improvement Activities (formerly Veneral Disease Research, Demonstrations, and Public Information and Education).

Authority

This program is authorized by section 318(b) of the Public Health Service Act (42 U.S.C. 247c(b)) as amended. Regulations governing programs for preventive health services are codified at 42 CFR Part 51b, Subparts A and F. The Catalog of Federal Domestic Assistance Number is 13.978.

Eligible Applicants

Official health agencies of any State, political subdivisions of any State, the District of Columbia, Puerto Rico, Virgin Islands, Guam, the Trust Territory of the Pacific Islands, the Northern Mariana Islands, and American Samoa, and any other public or nonprofit private entities are eligible to apply for a grant.

Program Objectives

The objectives of this grant program are to develop, improve, and evaluate methods for the prevention and control of STDs through demonstrations and applied research; to develop, improve, apply, and evaluate methods and strategies for public information and education about STD; and to support particularly deserving STD public information and education programs. Applied research as used in the context of this announcement means the process of developing and evaluating operational approaches and solutions to practical STD control problems by formulating appropriate models and hypotheses and testing them in the field.

Availability of Funds

Approximately $2,800,000 to $3,000,000 is available in Fiscal Year 1986 to award up to 24 continuation grants. The average award is expected to be $131,000, ranging from approximately $32,000 to $250,000. Grants are usually funded for 12 months in a 2- to 5-year project period. Funding estimates outlined above may vary and are subject to change. No new applications for these funds are being accepted.

Application Review

Continuation awards within the project period are made on the basis of satisfactory progress in meeting project objectives and on the availability of funds.

Applications are subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (30-day review).

Where to Obtain Additional Information

Information on application procedures, copies of application forms, and other material may be obtained from Betty Feeley, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE, Room 321, Atlanta, Georgia 30305, or by calling (404) 262–6575 or FTS 236–6575. Technical assistance may be obtained from Jack Kirby, Division of Sexually transmitted Diseases, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia, 30333, telephone (404) 329–2550 or FTS 236–2550.

Dated: June 13, 1986.

Robert L. Foster,

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

[FR Doc. 86–13966 Filed 6–19–86; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket Nos. 86P–0186 and 86P–0204]

Petitions Requesting Exclusivity for Certain Chlorhexidine Gluconate Products

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the filing of two petitions requesting a period of marketing exclusivity for certain topical antimicrobial cleansing agents containing chlorhexidine gluconate. FDA is giving notice of the filing of these petitions to all interested persons because, should FDA decide to grant the petitions, this decision may affect the date when approvals for marketing of generic versions of these chlorhexidine gluconate products may be made effective.

DATE: Comments by July 21, 1986.

ADDRESS: Requests for a copy of the petitions and written comments regarding the petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Carol A. Kimbrough, Center for Drugs and Biologics (HFN–364), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8046.

SUPPLEMENTARY INFORMATION: On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984. This statute amends the Federal Food, Drug, and Cosmetic Act (the act) by authorizing the agency to accept abbreviated new drug applications (ANDA's) for most previously approved new drug products. This legislation also provides for extending the term of a patent which claims a product, use, or method of manufacture that was subject to a regulatory review period in accordance with the act. Further, the legislation provides for periods of exclusive marketing ("exclusivity") of certain new drug products approved in an application (or a supplement to an application) submitted under section 505(b) of the act (21 U.S.C. 355(b)). An ANDA or paper new drug application (NDA) for such a drug may not be submitted, under some provisions or made effective, under other provisions, until the period of exclusivity ends.

The new drug products that have been granted periods of exclusivity under one of the several exclusivity provisions of the 1984 legislation are identified in the volume entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the list) and its monthly supplements. For each such drug product, the period of exclusivity is shown. Further, the list shows those products that are covered by a patent and when the patent expires.

The agency believes that all patent and exclusivity information appearing in the list is correct, and expects that such information appearing in any future supplements to the list will also be correct. However, interested persons may disagree with the agency's findings and believe that FDA has excluded patent or exclusivity information that should have been included, or included patent or exclusivity information that should have been excluded. Accordingly, FDA has established a policy that, whenever an interested person submits a citizen petition requesting such inclusion or exclusion, the agency will publish a notice in the **Federal Register** of the avaliability of the petition. This publication is constructive notice to all interested persons that they may be affected by the petition and gives them an opportunity to submit their comments on the petition to the agency. Persons potentially affected include holders of approved ANDA's or approved paper NDA's the effective dates of which might be changed by a decision to grant the petition, persons who have pending ANDA's or paper NDA's or who contemplate submitting such applications that, when approved, would have effective dates that will be determined by the decision on the petition or, in some cases, persons whose right to submit such applications may be affected. Where a petition seeks a change in a decision to grant exclusivity, the applicant granted exclusivity has an obvious interest in the issue.

In accordance with FDA's policy, the agency is announcing the filing of two petitions in which Xttrium Laboratories seeks exclusivity for certain topical antimicrobial cleansing agents. Petition 86P–0186 requests exclusivity for an aerosol product and a solution product, each containing 4 percent chlorhexidine gluconate. Petition 86–0204 requests exclusivity for two solution products, one containing 2 percent chlorhexidine gluconate and the other containing 2.5 percent chlorhexidine gluconate. In each petition, Xttrium states that the glove juice studies and health care hand washing studies it was required to conduct were new clinical investigations meeting all the requirements for 3-year exclusivity under section 505(j)(4)(D)(iii) of the act.

FDA is reviewing the merits of these petitions and, by this notice, is giving anyone who may be affected by these petitions an opportunity to submit comments within 30 days.

Interested persons may, on or before July 21, 1986, submit to the Dockets Management Branch (address above) written comments on the petitions. These comments will be considered in preparing an agency response to the petitions. Two copies of any comments are to be submitted for each petition to which comments are addressed, except that individuals may submit one copy. Comments on the petition regarding the 4-percent chlorhexidine gluconate products should be identified with docket number 86P–0186 as shown in brackets in the heading of this document. Comments on the petition regarding the 2- and 2.5-percent chlorhexidine products should be identified with docket number 86P–0204 as shown in brackets in the heading of this document. Comments addressed to both petitions should be identified with both docket numbers. The petitions and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. Requests for a single copy of either or both petitions should contain the appropriate docket number or numbers and be sent to the Dockets Management Branch.

Dated: June 16, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–13950 Filed 6–19–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86F–0171]

Reynolds Metals Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Reynolds Metals Co. has filed a petition proposing that the food additive regulations by amended to provide for the safe use of *alpha*-tridecyl-*omega*-hydroxypoly(oxyethylene) phosphate; *alpha*-butyl-*omega*-hydroxypoly (oxyethylene)poly(oxypropylene), minimum molecular weight 1,000; and *alpha*-lauroyl-*omega*-hydroxypoly(oxyethylene) in the manufacture of metallic articles intended to contact food.

FOR FURTHER INFORMATION CONTACT: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. 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 6B3931) has been filed by Reynolds Metals Co., 2101 Reymet Rd., Richmond, VA 23237, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of *alpha*-tridecyl-*omega*-hydroxypoly (oxyethylene) phosphate; *alpha-butyl-omega*-hydroxypoly(oxyethylene)-poly(oxypropylene), minimum molecular weight 1,000; and *alpha*-lauroyl-*omega*-hydroxypoly(oxyethylene) in the manufacture of metallic articles intended to contact 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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: June 10, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-13947 Filed 6-19-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 84P-0279]

Food for Human Consumption; Canned Green Beans Deviating From Identity Standard; Further Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit issued to Rogers Walla Walla, Inc., and Continental Can Co., Inc., to market test experimental packs of canned green beans containing added zinc chloride is being further amended to reflect a change in the name of the permit holders.

DATE: The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

FOR FURTHER INFORMATION CONTACT: Catharine R. Calvert, Center for Food Safety and Applied Nutrition (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0121.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to Rogers Walla Walla, Inc., P.O. Box 998, Walla Walla, WA 99362, and the Continental Can Co., Inc., 51 Harbor Place, Box Number 10004, Stamford, CT 06904-2004, to market test canned green beans containing added zinc chloride to retain the color of the test product (up to 75 parts per million of zinc in the finished food). The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to Rogers Walla Walla, Inc., and Continental Can Co., Inc., was published in the **Federal Register** of September 20, 1984 (49 FR 36925).

Notice of an extension and amendment of the temporary permit was published in the **Federal Register** of March 13, 1986 (51 FR 8707). The amended permit provides for market testing on an annual basis of 500,000 cases of number 303 cans and 250,000 cases of number 10 cans. These quantities are in addition to the 210,000 cases of number 303 cans and 190,000 cases of number 10 cans of the test product provided for by the original permit, but which have not been distributed.

Since the permit was issued, Rogers Walla Walla, Inc., has been acquired by American Fine Foods, Inc., Payette, ID 83661. Rogers Walla Walla, Inc., and American Fine Foods, Inc., jointly have requested that the temporary permit be amended to reflect this change. Accordingly, FDA, under provisions of 21 CFR 130.17(f), is further amending the temporary permit to indicate that American Fine Foods, Inc., is one of the permit holders, jointly with Continental Can Co., Inc. The agency will permit the use of existing labels which declare the packer as Rogers Walla Walla, Inc., until such labels have been exhausted. When new labels are printed for the test product, the new company name, American Fine Foods, Inc., must be declared as the packer. All other conditions and terms of this permit remain the same. The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

Dated: June 13, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-13949 Filed 6-19-86; 8:45 am]

BILLING CODE 4160-01-M

Health Care Financing Administration

Medicaid Program; Notice of Hearing: Reconsideration of Disapproval of a Arkansas State Plan Amendment

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing on July 16, 1986 in Dallas, Texas to reconsider our decision to disapprove Arkansas State Plan Amendment 85-19.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the Docket Clerk (within 15 days after publication).

FOR FURTHER INFORMATION CONTACT: Docket Clerk, Hearing Staff, Bureau of Eligibility, Reimbursement and Coverage, 365 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207, Telephone: (301) 594-8261.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove a Arkansas State Plan Amendment.

Section 1116 of the Social Security Act and 45 CFR Parts 201 and 213 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid Agency that informs the agency of the time and place of the hearing and the issues to be considered. (If we subsequently notify the agency of additional issues which will be considered at the hearing, we will also publish that notice.)

Any individual or group that wants to participate in the hearing as a party must petition the Hearing Officer within 15 days after publication of this notice, in accordance with the requirements contained in 45 CFR 213.15(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the Hearing Officer before the hearing begins in accordance with the requirements contained in 45 CFR 213.15(c)(1).

If the hearing is later rescheduled, the Hearing Officer will notify all participants.

The issues in this matter is whether Arkansas' proposed plan which would provide coverage of personal care services for Medicaid recipients residing in residential care facilities (RCFs) under a non-risk contract with the RCF is in violation of sections 1902(a)(4)(A), 1902(a)(19), and 1902(a)(30) of the Social Security Act and the implementing regulations at 42 CFR 434.12(b) and 447.362, respectively.

The State of Arkansas has failed to provide detailed information which is required by Federal regulation for determining whether the State plan provides for methods and procedures for the proper and efficient operation of the plan, and to assure that payments are consistent with efficiency, economy, and quality of care in accordance with Federal law. Specifically, Arkansas has failed to specify the capitation fee under the non-risk contract as required by 42 CFR 434.12(b). Therefore, HCFA has