4. Evidence of commitment and ability to develop an innovative design for urine collection and testing.

This CRADA is proposed and implemented under the 1986 Federal Technology Transfer Act: Pub. L. 99–502.

The responses must be made to: Nancy C. Hirsch, Technology Transfer Coordinator, National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mailstop C–19, Atlanta, GA 30333.

Dated: June 17, 1993.

Robert L. Foster,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–14749 Filed 6–22–93; 8:45 am]

BILLING CODE 4160–18–P

Food and Drug Administration

[Docket No. 93F-0165]

R.T. Vanderbilt Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that R.T. Vanderbilt Co., Inc., has filed a petition proposing that the food additive regulations be amended to correct an error in nomenclature. The amendment would add dipentamethylenethiuram hexasulfide for use as an accelerator in the production of rubber articles intended for repeated food-contact use, and remove the erroneous listing of dipentamethylenethiuram tetrasulfide from the regulation.

FOR FURTHER INFORMATION CONTACT: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS–216), 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 3B4370) has been filed by R.T. Vanderbilt Co., Inc., P.O. Box 5150, Norwalk, CT 06856–5150. The petition proposes that the food additive regulations in § 177.2600 *Rubber articles intended for repeated use* (21 CFR 177.2600) be amended to correct an error in nomenclature. The amendment would list dipentamethylenethiuram hexasulfide for use as an accelerator in the production of rubber articles intended for repeated food-contact use, and remove the erroneous listing of dipentamethylenethiuram tetrasulfide from the regulation.

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: June 15, 1993.

L. Robert Lake,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–14764 Filed 6–22–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93F–0180]

Sumitomo Chemical America, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Sumitomo Chemical America, Inc., has filed two petitions proposing that the food additive regulations be amended to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl) ethyl]phenyl acrylate as an antioxidant in the manufacture of polypropylene and styrene block polymers that contact food.

FOR FURTHER INFORMATION CONTACT: Daniel N. Harrison, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

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 two petitions (FAP 3B4357 and 3B4359) have been filed by Sumitomo Chemical America, Inc., 345 Park Ave., New York, NY 10154. The petitions propose to amend the food additive regulations to provide for the safe use of 2,4-di-*tert*-pentyl-6-[1-(3,5-di-*tert*-pentyl-2-hydroxyphenyl)ethyl]phenyl acrylate as an antioxidant in the manufacture of polypropylene and styrene block polymers that 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).

Dated: June 15, 1993.

L. Robert Lake,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–14763 Filed 6–22–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases

AGENCY: Public Health Service, HHS.

ACTION: Final notice.

SUMMARY: Section 602 of Public Law 102–585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides discounts on covered outpatient drugs to eligible entities. Section 340B(a)(5)(A) provides that a drug purchase shall not be subject to both a discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act. The Department is directed to establish a mechanism to assure that covered entities comply with this prohibition. The purpose of this notice is to announce the final mechanism to prevent duplicate discounts and rebates.

The proposed mechanism was announced in the **Federal Register** at 58 FR 27293 on May 7, 1993. A comment period of 30 days was established to allow public comment on the proposed mechanism. Two comments were received. Both comments concerned issues involving implementation of the mechanism and did not raise substantive issues concerning the mechanism itself; therefore, we will address both comments in the Effective Date section. The mechanism, in its final form, is adopted as proposed.

FOR FURTHER INFORMATION CONTACT: Marsha Alvarez, R.Ph., Director, Office of Drug Pricing Program, Bureau of Primary Health Care, Health Resources and Services Administration, Room 7A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Phone: (301) 443–0004

DATES: The Department proposed to begin implementation of the mechanism on July 1, 1993, if the Public Health Service (PHS) could provide the State Medicaid agencies with the Medicaid

provider numbers for all covered entities. One comment addressed the necessity for a date by which PHS could, with certainty, provide the numbers to the States.

The Department has developed an implementation plan which involves providing covered entity Medicaid provider numbers to the State Medicaid agencies on a monthly basis for July, August, and September, 1993. From October, 1993, until June 30, 1994, the files will be updated on a quarterly basis. Thereafter, the files will be updated annually.

As outlined in the first notice, all State Medicaid drug utilization data for the third calendar quarter, due to manufacturers by November 30, 1993, would exclude rebates for discounted drugs sold to PHS covered entities. For claims paid by Medicaid prior to July 1, 1993, State agencies will bill manufacturers for rebates on all drugs paid by Medicaid.

SUPPLEMENTARY INFORMATION: The other comment dealt with entity participation in the PHS drug discount program prior to their exclusion from the Medicaid rebate program. Entities that utilize Medicaid billing systems that include pharmacy in their all-inclusive rates or do not submit Medicaid claims for covered outpatient drug reimbursement do not generate Medicaid rebates and have no need to participate in the mechanism to prevent duplicate discounts and rebates. These entities may request drug discounts retroactive to December 1, 1992, and may accept further drug discounts as soon as possible.

Those entities which bill Medicaid separately for covered outpatient drugs can only accept a discount on those drugs for which no claims for Medicaid reimbursement were sent to their respective State Medicaid agencies. They may accept the discounted price once their Medicaid provider numbers are received by the Drug Pricing Program, and the Program provides these numbers to the respective State Medicaid agencies.

Dated: June 16, 1993.

William A. Robinson,

Acting Administrator, Health Resources and Services Administration.

[FR Doc. 93-14767 Filed 6-22-93; 8:45 am]

BILLING CODE 4160-15-M

Substance Abuse and Mental Health Services Administration

Peer Review Appeals System

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice

SUMMARY: This Notice provides the procedures for an appeals process that the Substance Abuse and Mental Health Services Administration (SAMHSA) will use to resolve concerns that arise from perceived shortcomings or errors in the substance or procedure of expert peer review of grant and cooperative agreement applications.

ADDRESSES: The public is invited to provide written comments on these procedures; written comments should be sent to Jane A. Taylor, Ph.D., Deputy Director for Review Policy and Extramural Operations, Office of Extramural Programs, SAMHSA, 12C-26 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; telephone 301-443-4266.

SUPPLEMENTARY INFORMATION: Public Law 102-321, the ADAMHA Reorganization Act of 1992, enacted on July 10, 1992, amended the Public Health Service (PHS) Act to establish the SAMHSA. Section 504 of the PHS Act, as amended, provides for the conduct of peer and Advisory Council review of grants and cooperative agreements for substance abuse and mental health services prevention and treatment programs in SAMHSA.

The mission of SAMHSA is to reduce the incidence and prevalence of mental disorders and substance abuse and improve treatment outcomes for persons suffering from addictive and mental health problems and disorders.

The Administrator is authorized to award grants to, and enter into cooperative agreements with, public and private nonprofit entities to support demonstration projects, evaluations, systems improvements, services delivery, and the dissemination of information on substance abuse and mental health services for the delivery of these services.

SAMHSA has instituted an appeals policy to allow applicants the opportunity to request an examination of their concerns about the referral and peer review of their applications for grants and cooperative agreements. The policy is implemented through a two-tiered process and applies to the referral and review of all competing applications for grants and cooperative agreements. The policy does not apply to funding decisions. This Notice provides a summary of the procedures for operation of the SAMHSA Peer Review Appeals System.

SAMHSA Peer Review Appeals System

Substance Abuse and Mental Health Services Administration

Center For Substance Abuse Prevention (CSAP)

Center For Substance Abuse Treatment (CSAT)

Center For Mental Health Services (CMHS)

The SAMHSA has initiated a two-tiered appeals process whereby applicants may request an examination of their concerns about the referral and peer review of their applications for grants and cooperative agreements.

This process is intended to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review, i.e., from receipt and assignment of an application through its review by a National Advisory Council. Such concerns may involve refusal to accept an application; a disputed assignment of the application to an initial review group or to a particular Center; perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more members; apparent factual errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and perceived inappropriate handling of the review of the application.

However, the appeals process is not intended to resolve differences of opinion between peer reviewers and the project director; to provide a mechanism for allowing project directors to submit information that should have been presented in the original proposal; or to provide a forum for disputing priority score determinations in the absence of specific and substantive evidence pointing to a flawed review.

The appeals process will not supersede or bypass the peer review process, but if serious shortcomings are found to have occurred in the review of an application, they will be rectified by one of the following actions: review by the same or another initial review group; special consideration by the National Advisory Council; or administrative action authorized by the Center Director or designated staff.

Applicants are strongly urged to communicate and discuss their concerns regarding peer review with appropriate staff. However, if applicants are still dissatisfied after a response is received to their communications, they also may request a further examination of these concerns.

Under the appeals system, all concerns must first be communicated to the unit which, at the time, is responsible for the application. Appropriate officials will thoroughly examine the applicants' concerns,