availability, costs, and scope of private health insurance benefits among Americans;

- Examining the effects of changes in how chronic care and disability are managed and financed;
- Evaluating the growing impact of managed care and of enrollment in different types of managed care plans; and
- Examining access to and costs of health care for common diseases and conditions, prescription drug use, and other health issues.

Statisticians and researchers will use these data to make important generalizations on the civilian noninstitutionalized population of the United States, as well as to conduct research in which the family is the unit of analysis.

Method of Collection

The data will be collected using a combination of modes. For example, the AHCPR intends to introduce study participants to the survey through advance mailings. The first contact will provide the household with information regarding the importance and uses of the information obtained. The AHCPR will then conduct five (in-person) interviews with each household to obtain health care use and expense data. Lastly, the AHCPR will conduct one telephone interview with each household to obtain tax and asset information. Data will be collected using a computer-assisted personal interviewing method (CAPI). In certain cases, AHCPR will conduct interviews over the telephone, if necessary. Burden estimates follow:

Initial Number of Respondents: 10,000.

Panel 3: 4800.

Panel 4: 5200.

Number of Surveys Per Respondent: 6.

Average Burden Per Respondent: 9.0 hours.

Estimated Burden Total: 81,100 hours.

Panel 3: 39,050 hours.

Panel 4: 42,050 hours.

Request for Comments

Comments are invited on: (a) the necessity of the proposed collection; (b) the accuracy of the Agency's estimate of 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 the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Copies of these proposed collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above).

Dated: November 4, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97–29837 Filed 11–12–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Notice of Meetings

In accordance with section 10(a) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2) announcement is made of the following advisory subcommittees scheduled to meet during November 1997:

Name: Health Services Research Initial Review Group (Subcommittees: Health Systems Research, Health Care quality and Effectiveness Research, Health Care Technology and Decision Sciences, and Health Research Dissemination and Implementation).

Date and Time: November 19, 1997, 8:00 a.m.

Place: Bethesda Hyatt Hotel, One Metro Plaza, Bethesda, Maryland 20816.

Open November 19, 8:00 a.m. to 8:30 a.m.

Closed for remainder of meetings.

Purpose: The Health Systems Research Subcommittee is charged with the initial review of research applications relating to cost and financing of health care, health care markets, organizational and delivery system issues, and the provider workforce. The Health Research Dissemination and Implementation Subcommittee is charged with the initial review of research applications relating to behavior change, demonstrations and interventions, consumer decision-making, dissemination, health professional and consumer education, and translation of research findings. The Health Care Technology and Decision Sciences Subcommittee is charged with the initial review of research applications relating to the development, refinement, assessment, cost-effectiveness, and application of health care technologies. The Health Care Quality and Effectiveness Research Subcommittee is charged with the initial review of research applications relating to clinical outcomes and effectiveness, quality and cost-effectiveness of health care, effectiveness research, evidence-based medicine, and quality of care research.

Agenda: The open sessions of these meetings on November 19, from 8:00 a.m. to 8:30 a.m., will be devoted to business meetings covering administrative matters and reports. During the closed sessions, the Subcommittees will be reviewing research and demonstration grant applications relating to the delivery, organization, and financing of health services. In accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C., 552b(c)(6), the Administrator, AHCPR, has made a formal determination that these latter sessions will be closed because the discussions are likely to reveal personal information concerning individuals associated with the applications. This information is exempt from mandatory disclosure.

Anyone wishing to obtain rosters of members, minutes of the meetings, or other relevant information should contact Sheila S. Simmons, Committee Management Officer, Agency for Health Care Policy and Research, Suite 400, Executive Office Center, 2101 East Jefferson Street, Rockville, Maryland 20852, Telephone (301) 594–1452 ext. 1627.

Agenda items for all meetings are subject to change as priorities dictate.

Dated: November 4, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97–29836 Filed 11–12–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Exchange of Letters Between the Food and Drug Administration and the Australian Therapeutic Goods Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of an exchange of letters (EOL) between FDA and the Australian Therapeutic Goods Administration. The purpose of the EOL is to facilitate the exchange of documents and information concerning a drug or biological preparation that is considered for orphan status.

DATES: The agreement became effective August 12, 1997.

FOR FURTHER INFORMATION CONTACT: Marlene E. Haffner, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: It is FDA's policy that EOL's be used in lieu of a formal agreement when the actions contemplated require only a limited resource expenditure and do not rise to the significance of a formal agreement. For example, an exchange of letters could formalize an understanding that each agency will provide the other with documents that are available upon request to any member of the public. Each letter should set out only the actions to be carried out by the agency signing the letter and not mutual considerations. FDA uses the same clearance for EOL's as it does for memoranda of understanding (MOU's). Therefore, MOU's in accordance with 21 CFR 20.108 (c), which states that all written agreements and MOU's between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this EOL.

Dated: November 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

The EOL's are set forth as follows:

Exchange of Letters Between the Food and Drug Administration and the Australian Therapeutic Goods Administration

225–97–8003

August 12, 1997
Mr. Terry Slater
National Manager
Therapeutic Goods Administration
Commonwealth Department of Health and Family Services
P.O. Box 100
Woden ACT 2606
AUSTRALIA

Dear Mr. Slater:

The U.S. Food and Drug Administration is pleased to cooperate with your government in facilitating the exchange of documents and information concerning a drug or biological preparation that your government is considering for orphan product status. We hope that this cooperation will facilitate and expedite access to needed therapy for Australian patients with rare diseases.

Upon request from the Australian Therapeutic Goods Administration (TGA), and to the extent permitted by U.S. law and FDA regulations, and as appropriate, with the permission of the U.S. sponsor, the FDA Office of Orphan Products Development (OPD) intends to provide to the TGA a copy of the U.S. designation request and review performed by the OPD on a particular product, whether such orphan designation request has or has not been granted.

Upon request from the TGA, and under the same terms and conditions noted in the preceding paragraph, the Center for Drug Evaluation and Research (CDER) or the Center for Biologic Evaluation and Research (CBER) intends to provide summary information concerning evaluation and approval of a particular product. OPD expects to be receptive to requests for assistance in seeking permission of the sponsor to permit TGA to utilize the necessary information. We understand that the reports and information FDA provides will form the basis for a similar orphan product evaluation for Australia.

Information provided by FDA pursuant to this arrangement will be provided in confidence to the TGA. The information will be provided in accordance with FDA law and regulations, including privacy and confidentiality requirements, and only with assurances of TGA's authority and commitment to protect the information from public disclosure in Australia. Copies of designation or evaluation reports will be provided to the TGA in conformance with the requirements of Part 20 of Title 21, U.S. Code of Federal Regulations, and with the written consent (where appropriate) of the U.S. sponsor of the designation request or product approval application.

For the purpose of coordination, we propose that the respective liaison officials be:

For the FDA:

Director, Office of Orphan Products Development
Food and Drug Administration/HF–35
5600 Fishers Lane Room 8–73
Rockville, Maryland 20857
U.S.A.
Telephone: 301–827–3666
FAX: 301–443–4915

For the Australian TGA:

Director, Drug Safety and Evaluation Branch
Therapeutic Goods Administration
P.O. Box 100
Woden, ACT 2606
Australia
Telephone: 61 2 6232 8100
FAX: 61 2 6232 8140

To help ensure that this information exchange program works well and meets our mutual needs and requirements, we feel that it is important that, at appropriate intervals, and by mutual concurrence, a discussion or meeting take place between representatives of our two agencies to assess the activities and the provisions outlined in this letter.

We anticipate that these arrangements will provide a sound basis on which further cooperative arrangements between us on products for patients with rare diseases will develop.

Sincerely,
Marlene E. Haffner, M.D., M.P.H.
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development

Marlene E. Haffner, MD, MPH
Rear Admiral, United States Public Health Service
Director, Office of Orphan Products Development
5600 Fishers Lane, HF–35
Room 8–73
Rockville, MD 20857 USA

Dear Dr. Haffner:

The purpose of this letter is to formalise our agreement regarding provision of information on orphan drugs by the U.S. Food and Drug Administration (FDA) U.S.A. to the Therapeutic Goods Administration (TGA), Department of Health and Family Services, Australia.

The TGA formally requests that the U.S. FDA provide orphan drug designation reports and orphan drug evaluation reports to the TGA.

In the spirit of co-operation, and on behalf of the TGA, I agree as follows:

1. Following receipt by the TGA of an application requesting orphan drug designation of a drug in Australia, the TGA will request from the Office of Orphan Drugs Development a copy of an orphan drug designation report for the drug.

This request will apply in cases where the drug has been granted orphan drug designation in the U.S. or where the drug has been refused orphan drug designation in the U.S.

2. Following receipt by the TGA of an application to register a product for which orphan designation has been granted for the drug in Australia, the TGA will request from the U.S. FDA a copy of the Center for Drug Evaluation and Research (CDER) evaluation reports or the Center for Biologics Evaluation and Research (CBER) evaluation report.

This request will apply in cases where a drug has been granted orphan drug designation in the U.S. and where an application to register a product containing that drug in the U.S. has been approved, refused, or is pending.

3. It is intended that where possible, the reports provided under this arrangement will form the basis of the evaluation of similar application sin Australia. Therefore, the reports must be sufficiently complete to enable appropriate evaluation of the product.
4. Information will be provided in accordance with agency regulations (including confidentiality requirements).
5. Copies of designation reports of evaluation reports will be provided to the TGA only after the written consent of the U.S. sponsor of the designation request or product registration application has been obtained, except as otherwise provided in FDA's regulations disclosure (21 CFR 20.89).
6. Liaison officers for the purpose of coordinating these provisions are as follows:

For the FDA:

Director, Office of Orphan Products Development
Food and Drug Administration/HF–35
5600 Fishers Lane, Room 8–73
Rockville, Maryland 20857
U.S.A.
Telephone: 301–827–3666
FAX: 301–443–4915

For the TGA:

Director, Drug Safety and Evaluation Branch
Therapeutic Goods Administration
P.O. Box 100
Woden, ACT 2606

Australia
Telephone: 61 2 6232 8100
FAX: 61 2 6232 8140

I am confident the implementation of these provisions will provide a sound basis on which to develop further cooperative arrangements between us on orphan drug products and to work toward a reciprocal arrangement in the future.

I look forward to your official confirmation these arrangements can be agreed.

Yours sincerely
Terry Slater
National Manager
Therapeutic Goods Administration
12 August 1997

[FR Doc. 97–29906 Filed 11–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0450]

Nalco Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nalco Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of an emulsifier blend containing sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate, and polyoxyethylene (20) sorbitan monolaurate as an anti-corrosive agent in boilers where steam may contact food.

DATES: Written comments on the petitioner's environmental assessment by December 15, 1997.

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

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

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 food additive petition (FAP 7A4540) has been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60568–1198. The petition proposes to amend the food additive regulations in § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of an emulsifier blend containing sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate, and polyoxyethylene (20) sorbitan monolaurate as an anti-corrosive agent in boilers where steam may contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before December 15, 1997, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, 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 28, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–29771 Filed 11–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 1997

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 1997, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject City, State	Effective date
Program-Related Convictions	
ADEFIHAN, TITILAYO O, MILWAUKEE, WI	11/20/97
ALEXANDER, EDNA DENISE, DEVINE, TX	11/20/97
ALLEN, ANDREW JACKSON, WINSLOW, AZ	11/20/97
AMICUCCI, DIANE CAROL, CARMEL, NY	11/20/97
BANDY, BRIAN DWAYNE, ASHLAND, KY	11/20/97
BARNES, DAVID L, HAMMOND, LA	11/20/97
BATRA, KRISHAN KUMAR, ODESSA, FL	11/20/97
BEAUDOIN, GERARD MARCEL JR, EGLIN AFB, FL	11/20/97
BROWN, YVONNE, ROCKVILLE CENTRE, NY	11/20/97
BROYLES, STEPHEN R, TAMPA, FL	11/20/97
BUDDE, MICHAEL J, COLUMBIA, IL	11/20/97