

assure the submission of more complete reports at the earliest possible time.

The agency recently published a proposal in the Federal Register of October 19, 1982 (47 FR 46622) that would substantially revise the regulations governing the new drug approval process. When FDA publishes a final rule based on the proposal, the agency may need to make changes in the draft guideline for filing Form FDA 1639, "Drug Experience Report," and in the form itself. Because Form FDA 1639 is now in use, and to avoid undue delay in making available a draft guideline that will be helpful to those who use the form, the agency believes it should make the draft guideline available at this time.

Interested persons may on or before May 31, 1983, submit written comments on this draft guideline to the Dockets Management Branch (address above), where a copy of the draft guideline has been placed on file for public display. Such comments will be considered in the preparation of a final guideline. Two copies of all comments shall be submitted, except that individuals may submit single copies of comments. Comments should be identified by the docket number found in brackets at the heading of this document. Comments received by the agency may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Requests for single copies of the draft guideline should be addressed to Judith K. Jones (address above).

Dated: January 21, 1983.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-2338 Filed 1-27-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 80N-0261]

#### Food Labeling Formats; Extension of Comment Period

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the comment period on its request for receipt of information on alternative food label formats for presenting nutrient information. The agency announced this request in a notice announcing a public meeting on the subject that was held December 2, 1982. The Society for Nutrition Education, the American Public Health Association, and the Vermont Department of Health requested an extension of the comment period.

**DATE:** Written comments by April 1, 1983.

**ADDRESS:** Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Raymond C. Stokes, Bureau of Foods (HFF-240), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1457.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of October 29, 1982 (47 FR 49092), FDA issued a notice announcing the second in a series of public meetings in collaboration with the U.S. Department of Agriculture (USDA) to discuss FDA's research project on communicating food label information. Alternative nutrition labeling formats and tentative plans for consumer research to evaluate the formats were presented and discussed at the meeting held on December 2, 1982. The notice asked for written comments by January 31, 1983.

The agencies have solicited design suggestions from the food industry, food and nutrition professionals, consumers, and other interested members of the public regarding the organization and display of label information, including consideration of such elements as the use of graphic and pictorial formats, layout, type size, and the use of colors and symbols. At the December 2, 1982 public meeting, the future research plan and the results of the work performed by Robert P. Gersin Associates, Inc., 11 E. 22nd St., New York, NY 10010, to create a number of alternative food label formats for presenting nutrient information was presented. The agencies encouraged comments on this information presented to the public.

Under 21 CFR 10.40(b)(3), the Society for Nutrition Education, the American Public Health Association, and the Vermont Department of Health requested an extension of the comment period. Reasons given were because the minerals were unavailable to the public until the December 2, 1982 meeting and because of the time constraints resulting from the holiday season during this comment period. In addition, the time allowed did not permit interested parties an adequate period to prepare responses to an issue of such complexity. The agencies also note that there was a delay in distribution of the transcript of the December 2, 1982 public meeting.

Therefore, because of the reasons discussed above, the agencies conclude that it is appropriate to extend the comment period until April 1, 1983.

Therefore, under 21 CFR 10.35(e), FDA is granting the requests for the extension.

Interested persons may, on or before April 1, 1983, submit to the Dockets Management Branch (address above) written comments regarding the subject notice. 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.

Dated: January 24, 1983.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 83-2330 Filed 1-26-83; 3:19 pm]

BILLING CODE 4160-01-M

[Docket No. 82F-0384]

#### Gulf Oil Corp.; Filing of Food Additive Petition

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Gulf Oil Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1 alkenyl olefins as components of paper and paperboard.

**FOR FURTHER INFORMATION CONTACT:** Geraldine E. Harris, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-473-5690.

**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 3A3679) has been filed by Gulf Oil Corp., Pittsburgh, PA 15219, proposing that the food additive regulations be amended to provide for the safe use of 1 alkenyl olefins as components of paper and paperboard.

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) (proposed December 11, 1979; 44 FR 71742).

Dated: January 14, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-2180 Filed 1-27-83; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 82C-0399]

**Polymer Technology Corp.; Filing of Color Additive Petitions**

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

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Polymer Technology Corp. has filed three color additive petitions proposing that the color additive regulations be amended to provide for the safe use of D&C Green No. 6, D&C Yellow No. 11 and D&C Red No. 17 for coloring contact lenses.

**FOR FURTHER INFORMATION CONTACT:** Andrew D. Laumbach, Bureau of Foods (HFF-334), 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. 706(b)(1), 74 Stat. 399-402 as amended (21 U.S.C. 376(b)(1))), notice is given that three color additive petitions (CAP's 3CO163, 3CO164, and 3CO165) have been filed by Polymer Technology Corp., 33 Industrial Way, Wilmington, MA 01887, proposing that the color additive regulations be amended to provide for the safe use of D&C Green No. 6, D&C Yellow No. 11, and D&C Red No. 17 in coloring contact lenses.

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) (proposed December 11, 1979; 44 FR 71742).

Dated: January 14, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 83-2069 Filed 1-27-83; 8:45 am]

BILLING CODE 4160-01-M

**Health Care Financing Administration**

**Medicaid Program; Hearing; Reconsideration of Disapproval of Wisconsin State Plan Amendment**

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

**ACTION:** Notice of hearing.

**SUMMARY:** This notice announces an administrative hearing on March 15, 1983 in Chicago, Illinois to reconsider two issues in our decision to partially disapprove Wisconsin State Plan Amendment 82-0096.

**DATE:** Request to participate in the hearing as a party must be received by 15 days after publication.

**FOR FURTHER INFORMATION CONTACT:** Docket Clerk, Bureau of Program Policy, G-20 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207, Telephone: (301) 594-8261.

**SUPPLEMENTARY INFORMATION:** This notice announces an administrative hearing to reconsider two issues in our decision to partially disapprove a Wisconsin 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 denial 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 additional 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 additional 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 relate to Wisconsin's proposals which provide inpatient psychiatric hospital services to categorically needy individuals age 22 to 64 and offer additional optional ambulatory services only to those medically needy individuals who are institutionalized. The Health Care Financing Administration disapproved these provisions on the basis that they violate existing statutory or regulatory requirements under the Medicaid program related to the unavailability of Federal Financial Participation (FFP) for expenditures for services provided to individuals age 22 to 64 in an institution for mental diseases (IMD) and to

comparability of services for all recipients within a covered medically needy group.

The notice to Wisconsin announcing an administrative hearing to reconsider our denial of portions of its state plan amendment reads as follows:

Mr. Kenneth Rentmeester,  
Administrator, Division of Health,  
Department of Health and Social  
Services, P.O. Box 309, 1 West Wilson  
Street, Madison, Wisconsin 53702.

Dear Mr. Rentmeester: This is to advise you that your request for reconsideration of the decision to disapprove portions of Wisconsin State Plan Amendment 82-0096 was received on December 28, 1982. You have requested a reconsideration whether the proposals to provide inpatient psychiatric hospital services to categorically needy individuals age 22 to 64 and to offer additional optional ambulatory services only to those medically needy individuals who are institutionalized conform to the requirements for approval under the Social Security Act and pertinent Federal requirements.

I am scheduling a hearing on your request to be held on March 15, 1983 at 10 a.m. in the 8th Floor Conference Room, 175 West Jackson Boulevard, Chicago, Illinois. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties.

I have designated Mr. Albert Miller as the presiding official. Although Mr. Miller will conduct the hearing and make a recommendation of his findings and proposed decision, I shall carefully review his findings and issue the final decision on the matter. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the Docket Clerk of the names of the individuals who will represent the State at the hearing. The Docket Clerk can be reached on (301) 594-8261.

Sincerely yours,

Carolyne K. Davis, Ph. D.

(Section 1116 of the Social Security Act (42 U.S.C. 1316))

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program)

Dated: January 24, 1983.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

[FR Doc. 83-2373 Filed 1-27-83; 8:45 am]

BILLING CODE 4120-03-M

**National Institutes of Health**

**Heart, Lung, and Blood Research Review Committee A; Meeting**

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Heart, Lung, and Blood Research Review Committee A, National Heart, Lung, and Blood Institute, National Institutes of Health, on March 25-26, 1983, in Building 31, Conference Room 7, 9000

Rockville Pike, Bethesda, Maryland 20205.

This meeting will be open to the public on March 25, 1983 from 8:30 AM to approximately 9:30 AM to discuss administrative details and to hear reports concerning the current status of the National Heart, Lung, and Blood Institute. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on March 25, from approximately 9:30 AM until adjournment on March 26, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Terry Bellicha, Chief, Public Inquiry Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4-A21, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-4236, will provide summaries of the meeting and rosters of the committee members.

Dr. Peter M. Spooner, Executive Secretary, Heart, Lung, and Blood Research Review Committee A, Westwood Building, Room 648, National Institutes of Health, Bethesda, Maryland 20205, phone (301) 496-7265, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, Heart and Vascular Diseases Research; 13.838, Lung Diseases Research; National Institutes of Health.)  
Dated: January 17, 1983.

Betty J. Beveridge,

*NIH Committee Management Officer.*

[FR Doc. 83-2346 Filed 1-27-83; 8:45 am]

BILLING CODE 4140-01-M

#### Heart, Lung, and Blood Research Review Committee B; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Heart, Lung, and Blood Research Review Committee B, National Heart, Lung, and Blood Institute, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205, on March 25-26, 1983, in Building 31, Conference Room 9.

This meeting will be open to the public on March 25, 1983, from 8:30 AM to approximately 10:00 AM to discuss administrative details and to hear reports concerning the current status of the National Heart, Lung, and Blood

Institute. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on March 25, 1983, from approximately 10:00 AM to adjournment on March 26, for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Terry Bellicha, Chief, Public Inquiry Reports Branch, National Heart, Lung, and Blood Institute, Building 31, Room 4A21, National Institutes of Health, Bethesda, Maryland 20205, (301) 496-4236, will provide summaries of the meetings and rosters of the committee members.

Dr. Louis M. Ouellette, Executive Secretary, NHLBI, Westwood Building, Room 554, National Institutes of Health, Bethesda, Maryland 20205, phone (301) 496-7915, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, Heart and Vascular Diseases Research; and 13.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: January 17, 1983.

Betty J. Beveridge,

*NIH Committee Management Officer.*

[FR Doc. 83-2349 Filed 1-27-83; 8:45 am]

BILLING CODE 4140-01-M

#### Microbiology and Infectious Diseases Advisory Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Microbiology and Infectious Diseases Advisory Committee, National Institute of Allergy and Infectious Diseases, February 24-25, 1983, at the Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20016.

The meeting will be open to the public from 8:30 a.m. to approximately 9:15 a.m. on February 24 for review of policies and procedures and routine business of the Committee. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Pub. L. 92-463, the meeting of the Committee will be closed to the public for the review, evaluation, and discussion of individual grant applications. It is anticipated that this will occur from 9:15 a.m. until adjournment on February 24 and again

from 8:30 a.m. until adjournment on February 25.

These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. Robert L. Schreiber, Chief, Office of Research Reporting and Public Response, National Institute of Allergy and Infectious Diseases, Building 31, Room 7A-32, National Institutes of Health, Bethesda, Maryland 20205, telephone (301) 496-5717, will provide summaries of the meetings and rosters of the Committee members as required.

Dr. Susan B. Spring, Executive Secretary, Microbiology and Infectious Diseases Advisory Committee, NIAID, NIH, Westwood Building, Room 706, telephone (301) 496-7465, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.855, Pharmacological Sciences; 13.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: January 17, 1983.

Betty J. Beveridge,

*NIH Committee Management Officer.*

[FR Doc. 83-2347 Filed 1-27-83; 8:45 am]

BILLING CODE 4140-01-M

#### National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the National Arthritis, Diabetes, and Digestive and Kidney Diseases Advisory Council and its subcommittees on February 9, 10, and 11, 1983 in Conference Room 6, Building 31, National Institutes of Health, Bethesda, Maryland. The meeting will be open to the public on February 9, from 8:30 a.m. to adjournment to discuss administration, management, and special reports. Attendance by the public will be limited to space available.

Meeting of the full Council and its subcommittees will be closed to the public as indicated below in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, for the review, discussion and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property such as patentable materials, and