

reasonable basis for such representations at the time they are made.

Part I also contains a proviso that allows the respondent to advertise and label plastic grocery store bags with a diamond-shaped symbol, and/or the statement, "Complies with Florida law," without violating Part I. Under Florida law, all plastic shopping bags must meet certain Florida standards for photodegradation, or breaking down when exposed to sunlight. Florida requires that such bags be printed with a diamond-shaped symbol indicating that the bags comply with Florida's standards.

Part I contains an additional proviso allowing the respondent to advertise and label plastic products as "compostable" or "degradable" without violating Part I of the proposed order. The respondent may use the terms in labeling, and in advertising that refers to the bags' "degradability," if the bags will in fact degrade or break down, along with leaf and grass yard waste, into usable compost (soil-conditioning material) in yard waste composting programs. In addition, to avoid possible confusion about the benefit of a compostable product degrading in sanitary landfills, the proviso also requires the respondent to disclose clearly, prominently, and in close proximity to such claims that the bags are not designed to degrade in landfills. In those states in which composting facilities are required for yard waste, the respondent may alternatively disclose that its bags are only designed to degrade in yard waste composting facilities. Furthermore, the respondent must also disclose either that yard waste composting programs may not be available in the consumer's area, or the approximate percentage of the U.S. population having access to such programs.

Part II of the proposed order provides that if the respondent uses in advertising or labeling such terms as "Safe for the Environment" or "Environmentally Friendly," or rearrangements of those terms or certain similar terms, it must have a reasonable basis consisting of competent and reliable scientific evidence that substantiates its representations. Further, to ensure compliance with this provision, the order requires the respondent to clearly disclose, with reasonable specificity, what it means by such terms.

Part III of the proposed order allows the respondent to use the terms cited in Parts I and II, or substantially similar terms, and not be in violation of the proposed order, if it is necessary for the respondent to comply with any federal

rule, regulation, or law governing the use of such terms in advertising or labeling.

The proposed order also requires the respondent to maintain materials relied upon to substantiate claims covered by the order, to distribute copies of the order to certain company officials and employees, to notify the Commission of any changes in corporate structure that might affect compliance with the order, and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,

Secretary.

**Concurring Statement of Commissioner Deborah K. Owen, in Which Commissioner Mary L. Azcuenaga and Commissioner Roscoe B. Starek, III Join**

The complaint in this case alleges that Mobil Oil Corporation ("Mobil") made certain unsubstantiated environmental claims about its plastic bags. The focus is on claims of degradability. Paragraph Four of the complaint lists certain statements taken from package labeling and from grocery bag labeling. Paragraph Five of the complaint alleges that through these statements, and others, Mobil Oil "represented, directly or by implication" two claims concerning the environmental benefits of its bags:

- a. Compared to other plastic bags, respondent's plastic bags offer a significant environmental benefit when consumers dispose of them as trash; and
2. Respondent's plastic bags will completely break down, decompose, and return to nature in a reasonably short period of time after consumers dispose of them as trash.

These claims are subsequently alleged in Paragraphs Six and Seven to be unsubstantiated.

Paragraph Four of the complaint contains one statement taken from Mobil's grocery bag labels that clearly relates to the issue of degradability: "degrades in sunlight." It also contains other statements that do not directly relate to the issue: "non-toxic when incinerated," "recyclable," and "no ground water contamination." Including the entire label in the complaint is useful for purposes of demonstrating the context in which the degradability claims were made. However, I would not want my vote in favor of this case to be construed as a determination, one way or the other, as to the latter claims. Based on the evidence presented in this

case, I do not understand the Commission's action there to preclude truthful claims relating to toxicity, ground water contamination, or recyclability, or to necessarily require, with respect to such claims, substantiation for both of the presentations in Paragraph Five. I would prefer that complaints distinguish more clearly between statements that are the basis of Commission action, and contextual material.

[FR Doc. 92-18892 Filed 8-7-92; 8:45 am]

BILLING CODE 6750-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control**

[Announcement Number 261]

**HIV-Related Tuberculosis Preventive Therapy Regimen (PTR) Demonstration Cooperative Agreements**

**Introduction**

The Centers for Disease Control (CDC), the Nation's prevention agency, announces the availability of Fiscal Year 1992 funds for a cooperative agreement program for tuberculosis (TB) and human immunodeficiency virus (HIV) preventive therapy regimen (PTR) demonstration projects.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority areas of HIV Infection and Immunization and Infectious Diseases. (For ordering a copy of Healthy People 2000, see the section Where to obtain Additional Information).

**Authority**

This program is authorized under sections 301(a) and 317(k) of the Public Health Service Act, (42 U.S.C. 241(a) and 247b(k)), as amended. Applicable program regulations are found in 42 CFR 51b, subpart A, which contains general provisions relating to this program.

**Eligible Applicants**

Eligible applicants include nonprofit and for-profit organizations. Thus, universities, colleges, research institutions, hospitals, other public and private organizations, state and local health departments or their bona fide agents or instrumentalities, alcohol and



substance abuse agencies, and small, minority- or women-owned businesses are eligible for these cooperative agreements. Applicants must be able to locate, monitor and evaluate a minimum of 75 dually-infected (TB/HIV) persons per year who can be administered the appropriate rifampin/pyrazinamide TB preventive therapy according to a prescribed regimen to be provided by CDC. A copy of the prescribed regimen will be included in the application kit.

#### Availability of Funds

Approximately \$1,200,000 is available in Fiscal Year 1992 to fund three to five awards. It is expected that the average award will be \$250,000, ranging from \$200,000 to \$450,000. Awards are expected to begin on or about September 28, 1992, for a 12-month budget period within a project period of up to four years. Funding estimates may vary and are subject to change. Continuation awards within the project period will be made on the basis of satisfactory progress and the availability of funds.

#### Purpose

The purpose of this program is to improve preventive treatment regimens for HIV-related *M. tuberculosis* through demonstration projects and applied research. Applied research, as used in the context of this announcement, means the process of the development and evaluation of practical operational approaches and solutions to HIV-related TB problems and the evaluation of new technology (e.g., new drugs, new drug regimens, new methods of testing drug feasibility, and applicability.)

Specific objectives of this project are to:

- Determined the efficacy of a rifampin/pyrazinamide drug regimen (as prescribed by CDC) in preventing the development of TB in HIV-infected persons at risk of developing TB.
- Describe the host factors that affect the efficacy of TB preventive therapy.
- Evaluate the acceptability and toxicity of the drug regimen in the prevention of TB.

#### National Goals

The ultimate goal of TB prevention and control efforts is disease elimination (a case rate of less than 0.1 per 100,000 population) by the year 2010, with an interim target goal of no more than 3.5 cases per 100,000 population by the year 2000.

The Healthy People 2000 national goals relating to TB and HIV infection are:

- Assess the impact of HIV infection on TB morbidity and mortality.

- Develop more effective tools for the diagnosis of TB infection and disease in persons with HIV infection.

- Determine optimal drug regimens for the treatment of TB in persons with HIV infection.

- Develop optimal TB preventive therapy regimens for dually-infected (TB/HIV) persons.

- Prevent TB disease among dually-infected (TB/HIV) persons.

#### Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A., and CDC shall be responsible for conducting activities under B.

#### A. Recipient Activities

- Develop and implement strategies that are applicable to TB/HIV-infected persons in the United States including: (a) methods and strategies to successfully identify, enroll, and administer appropriate preventive drug therapy to HIV-infected persons also infected with *M. tuberculosis*; and (b) methods to actively monitor and insure compliance with drug therapy, assess toxicity, and appropriately evaluate patients for up to 2 years after completion of preventive therapy.
- Identify and enroll a minimum of 75 dually-infected (TB/HIV) persons into the prescribed preventive therapy regimen.
- Implement specified follow-up procedures to monitor, for both efficacy and toxicity, in dually-infected (TB/HIV) persons receiving the prescribed preventive therapy.
- Develop and implement methods for the follow-up of dually-infected (TB/HIV) individuals identified but not receiving preventive therapy.
- Develop and implement an evaluation plan that measures the effectiveness of the trial regimen employed.
- Compile and disseminate findings.

#### B. CDC Activities

- Provide consultation and technical assistance in planning, developing, operating, and evaluating strategies.
- Provide and explain, to each of the recipients, the preventive therapy regimen designated for this study. A copy of the prescribed regimen is included in the application kit.
- Provide up-to-date scientific information and coordinate the exchange of information among recipients.
- Assist in data management, analysis, and the evaluation of programmatic activities.

- Assist recipients in collaborating with state and local health departments and other PHS-supported tuberculosis and HIV/AIDS projects.

- Assist in the preparation and publication of findings.

#### Evaluation Criteria

Each application will be reviewed and evaluated individually according to the following criteria (100 total points maximum):

- The ability of the applicant to determine the extent of TB and HIV infection in their area to include: (1) The number of TB cases; (2) the number of AIDS cases; (3) the number of persons with TB and AIDS/HIV infection; (4) the estimated prevalence of HIV seropositivity in various population groups; and (5) the realistic estimated prevalence of tuberculin reactivity among AIDS risk groups. (10 points)

- The ability of the applicant to satisfactorily identify, using epidemiologic information, the number of dually infected (TB/HIV) persons and to have realistic expectations as to the numbers of persons (must have a minimum of 75) that will be enrolled into the TB preventive therapy regimen. (10 points)

- The ability of the applicant to perform active follow-up procedures on all participants who receive preventive therapy (defined as persons who are currently receiving drugs or those who have completed the drug therapy portion of their treatment) including methods to deal with noncompliant patients; and the extent to which qualified and experienced personnel are available to carry out the proposed follow-up activities. (30 points)

- The extent to which the applicant's short- and long-term objectives are realistic, measurable, time-phased, and consistent with the purpose of the program. (15 points)

- The overall potential effectiveness of the applicant's proposed activities and methods for meeting the stated objectives. (20 points)

- The adequacy of the proposed plans to evaluate progress in implementing methods and achieving objectives. (15 points)

In addition, consideration will be given to the extent to which the budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of cooperative agreement funds.

#### Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Numbers are 93.947, Tuberculosis Demonstration, Research, Public and



Professional Education; and 93.118, Acquired Immunodeficiency Syndrome (AIDS) activities.

#### Other Requirements

##### Confidentiality

Applicants must have in place systems to ensure the confidentiality of all patient records.

##### Pre- and Post-test Counseling and Partner Notification

Recipients are required to provide HIV antibody testing to determine a person's HIV infection status; therefore, they must comply with state laws and regulations and CDC guidelines regarding pre- and post-test counseling and partner notification of HIV-seropositive patients, a copy of which will be included in the application kit. Recipients must also comply with state and local health department requirements relating to specific reportable diseases or conditions. Recipients must provide referrals for HIV diagnosis and treatment.

##### Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

##### Human Subjects

The applicant must comply with the Department of Health and Human Services regulations (45 CFR part 46) regarding the protection of human subjects. Assurances must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

##### HIV/AIDS Requirements

Recipients must comply with the document entitled "Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions" (June 1992), a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program review panel such as the one created by the state health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a government health department

consistent with the Content guidelines. The names of the review panel members must be listed on the Assurance of Compliance form CDC 0.113, which also will be included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

##### Application and Submission Deadline

The original and two copies of the application (Form PHS-5161-1) must be submitted to Elizabeth M. Taylor, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Mailstop E-14, Atlanta, GA 30305 on or before September 11, 1992.

##### A. Deadline

Applications shall be considered as meeting the deadline if they are:

1. Received on or before the deadline date, or
2. Sent on or before the deadline date and received in time for submission to the independent review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be acceptable as proof of timely mailing.)

##### B. Late Applications

Applications that do not meet the criteria in A.1. or A.2. are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

##### Where to Obtain Additional Information

A complete program description and information on application procedures, an application package, and business management technical assistance may be obtained from Lynn Mercer, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 300, Atlanta, GA 30305, (404) 842-6814.

Programmatic technical assistance may be obtained from Lawrence J. Geiter, Division of Tuberculosis Control, National Center for Prevention Services, Centers for Disease Control, Atlanta, GA 30333, (404) 639-2530.

Please refer to Announcement 261, HIV-Related Tuberculosis Preventive Therapy Regimen (PRT) Demonstration Cooperative Agreements, when requesting information or submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report, Stock No. 017-001-00474-0) or Healthy People 2000 (Summary Report, Stock No. 017-001-00473-1) referenced in the introduction of this document through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (Telephone (202) 783-3238).

Dated: August 4, 1992.

Robert L. Foster,

Acting Associate Director for Management and Operations, Centers for Disease Control.  
[FR Doc. 92-18857 Filed 8-7-92; 8:45 am]

BILLING CODE 4150-18-M

#### Food and Drug Administration

[Docket No. 92C-0293]

#### The Cosmetic, Toiletry, and Fragrance Association; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the Cosmetic, Toiletry, and Fragrance Association (CTFA) has filed a petition proposing that the color additive regulations be amended to provide for the safe use of FD&C Yellow No. 5 and its lakes for coloring drugs and cosmetics intended for use in the area of the eye.

**FOR FURTHER INFORMATION CONTACT:** Wesley Long, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9515.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (sec. 706(d)(1) (21 U.S.C. 376(d)(1))), notice is given that a petition (CAP 6C0205) has been filed by CTFA, 1101 17th St. NW., Suite 300, Washington, DC 20036. The petition proposes to amend the color additive regulations in §§ 74.1705 *FD&C Yellow No. 5* and 74.2705 *FD&C Yellow No. 5* (21 CFR 74.1705 and 74.2705) to provide for the safe use of FD&C Yellow No. 5 and its lakes for coloring drugs and cosmetics intended for use in the area of the eye.

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: August 4, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-18854 Filed 8-7-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92F-0285]

### Mitsui Toatsu Chemicals, Inc.; Filing of Food Additive Petition

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a petition has been filed on behalf of Mitsui Toatsu Chemicals, Inc., proposing that the food additive regulations be amended to provide for the expanded safe use of bis(p-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), 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 a petition (FAP 2B4330) has been filed on behalf of Mitsui Toatsu Chemicals, Inc., c/o 1001 G St. NW., Suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3295 *Clarifying agents for polymers* (21 CFR 178.3295) to provide for the expanded safe use of bis(p-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with 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: August 4, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-18855 Filed 8-7-92; 8:45 am]

BILLING CODE 4160-01-F

### Request for Nominations for Members on Public Advisory Committees; Science Board to the Food and Drug Administration

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting nominations for 10 members to serve on the Science Board (the board) to the Food and Drug Administration in the Office of the Commissioner. Elsewhere in this issue of the Federal Register, FDA is publishing a final rule announcing the establishment of this committee.

**DATES:** Nominations should be received on or before September 9, 1992.

**ADDRESSES:** All nominations for membership except for the consumer-nominated members should be sent to Susan L. Crandall (address below). All nominations for the consumer-nominated members should be sent to Phyllis Weller (address below).

#### FOR FURTHER INFORMATION CONTACT:

Regarding all nominations for membership, except for the consumer-nominated members: Susan L. Crandall, Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5839.

Regarding all nominations for the consumer-nominated members: Phyllis Weller, Office of Consumer Affairs (HFE-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5006.

**SUPPLEMENTARY INFORMATION:** FDA is requesting nominations for 10 members to serve on the board. The function of the board is to provide advice primarily to the agency's Senior Science Advisor and, as needed, the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in academia and industry. Additionally, the board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of the agency

sponsored intramural and extramural scientific research programs.

FDA is notifying the public that the agency's Senior Science Advisor, Elkan Blout, has prepared a list of prospective candidates from academia and industry. These individuals will be considered along with other nominations submitted to the agency in response to this Federal Register notice.

Persons nominated for membership shall be knowledgeable in the fields of chemistry, pharmacology, toxicology, clinical research, and other scientific disciplines. Members shall represent academia and industry. The committee may include one technically qualified member who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. Members shall be invited to serve for overlapping 4-year terms except for the first members appointed: Three shall serve for a term of 2 years, three for a term of 3 years, and four for a term of 4 years as designated at the time of appointment.

Interested persons may nominate one or more qualified persons for membership on the advisory committee. Nominations shall state that the nominee is willing to serve as a member of the advisory committee and appears to have no conflict of interest that would preclude committee membership. Potential candidates will be asked by FDA to provide detailed information concerning such matters as financial holdings, consultancies, and research grants or contracts to permit evaluation of possible sources of conflict of interest.

Selection of a representative of consumer interests is conducted through procedures that include use of a consortium of consumer organizations which has the responsibility for screening, interviewing, and recommending candidates for the agency's selection. Candidates, like all other candidates for membership on the committee, should possess appropriate qualifications to understand and contribute to the committee's work.

FDA has special interest in assuring that women, minority groups, and the physically handicapped are adequately represented on advisory committees and therefore extends particular encouragement to nominations for appropriately qualified female, minority, or physically handicapped candidates.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. App. 2) and 21 CFR Part 14, relating to advisory committees.