(1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest, 99155.

See also the CDC home page on the Internet web site at http://www.cdc.gov and the program and grants office web site for additional funding opportunities and electronic versions of all necessary forms (www.cdc.gov/od/pgo/forminfo.htm).

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: Gladys T. Gissentanna, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone Number: 770–488–2753, Email Address: gcg4@cdc.gov.

For program technical assistance, contact: Dr. Consuelo Beck-Sague, Office of Minority Health, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, Telephone Number: 404–639–3467, Email Address: cmb1@cdc.gov.

Dated: June 15, 1999.

Henry S. Cassell,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–15652 Filed 6–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Announcement Number 99090]

Intervention Research Addressing the Primary and Secondary Prevention Needs of HIV-Seropositive Injection Drug Users Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) announce the availability of fiscal year (FY) 1999 funds for a cooperative agreement program to support intervention research on the primary and secondary prevention needs of HIV-seropositive injection drug users (IDUs). This announcement addresses the ''Healthy People 2000'' priority area Human Immunodeficiency Virus (HIV) Infection.

The purpose of this announcement is to support intervention research for HIV-seropositive IDUs that leads to the development of effective, feasible, and sustainable interventions having three goals: (1) To prevent HIV transmission due to high risk sexual and drug injection behaviors; (2) to increase access to, use of, and maintenance in primary health care; and (3) to increase access to, use of, and adherence to HIV treatments, including prophylaxis to prevent opportunistic infections.

Consistent with this purpose, funding under this program will support: (1) One year for intervention refinement and piloting of intervention strategies and components, in collaboration with other funded sites; (2) three years for a multi-site randomized controlled trial to test behavioral/biomedical interventions and strategies for this population; and (3) one year for data analysis and dissemination of research findings.

The intervention proposed for the trial must be based on behavioral theory as well as: (1) Prior research on sexual and drug injection practices among IDUs that lead to HIV/STD risk; and (2) prior research or research data on either adherence to HIV treatment or access to health care. The ultimate goal of this research is the identification of successful intervention strategies for HIV-seropositive IDUs, with an emphasis on IDUs newly diagnosed as HIV seropositive (within the past three years). It is expected that these strategies will integrate behavioral and biomedical approaches and will lead to models that are appropriate for implementation in community settings (e.g., local health departments, community-based organizations, health maintenance organizations) and that are suitable for replication in other communities.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, state and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Public Law 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

Approximately $2,000,000 is available in FY 1999 to fund three to five awards. It is expected that the average award for the first year will be $500,000. An application requesting greater than $600,000, including indirect costs, in year one will not be considered for review and will be returned to the applicant.

Awards are expected to begin on or about **September 30, 1999**. Awards will be made for a 12-month budget period within a total project period of up to five years. It is anticipated that increased funding may be available in years 2–4 to support the randomized controlled trial and in year 5 to support data analysis and dissemination of research findings. Funding estimates may vary and are subject to change based on the availability of funds.

Continuation awards within the project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Funding Preference

In order to promote research and interventions that address the needs of diverse regions of the United States, geographic diversity may be a factor considered in funding decisions. The recruitment area for funded applicants may not overlap. In addition, applicants must demonstrate that intervention programs and research studies for HIV-seropositive IDUs that are currently being conducted in the applicant's catchment area will not jeopardize the success of the proposed research.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities identified under Recipient Activities and CDC and HRSA will be responsible for the activities identified under CDC and HRSA Activities.

1. Recipient Activities

a. Refine and pilot test intervention strategies and components.

b. Develop plans for active collaboration during the entire project with local health departments, medical service providers, members of the affected population, their service providers, and community organizations.

c. Develop research protocols and data collection instruments appropriate to conduct a multi-site randomized controlled intervention trial.

d. Develop plans to collect prospective cost data for the intervention to allow estimates of the

cost of replicating the intervention elsewhere.

e. Establish procedures to maintain the rights and confidentiality of study participants.

f. Submit research protocols to the recipient's Institutional Review Board (IRB).

g. Identify, recruit, and enroll at least 200 research participants according to the study protocol.

h. Collect biological specimens to verify HIV serostatus and assess the presence of sexually transmitted diseases and other blood borne pathogens.

i. Contribute blood specimens (at least every 6–12 months depending on the protocol requirements) for shipment and storage at a centralized repository system at CDC.

j. Summarize the data from the intervention trial, conduct data analyses, and disseminate findings in peer-reviewed journals and at professional meetings.

k. Meet three or four times each year with other funded sites, CDC, and HRSA to discuss research and intervention protocols.

l. Obtain certificate of confidentiality to protect research records.

2. CDC and HRSA Activities

a. Provide scientific and technical assistance and coordination, as requested, for all phases of the study.

b. As needed, participate in the analysis of data gathered from research projects and the reporting of results.

c. Facilitate group meetings with the sites to allow for the exchange of information and for input into the development and refinement of the research and intervention protocol.

d. Conduct site visits to assess program progress.

e. Assist in the development a research protocol for IRB review by each institution participating in the research project as well as the CDC IRB. CDC IRB also will review the projects on at least an annual basis until the research is complete.

f. Arrange meetings with the External Working Group (EWG) convened by CDC. The EWG is an independent advisory group made up of non-CDC experts who will provide input on the scientific, methodological, and ethical aspects of the research and intervention protocol. The EWG will act like a data safety monitoring board during the intervention trial.

g. Assist the sites in obtaining certificates of confidentiality to protect research records.

E. Application Content

You must document that this proposal is consistent with the Statewide Coordinated Statement of Need document from your area or provide a rationale for any discrepancies. Note: This initiative is supported, in part from funds provided under the Special Projects of National Significance Program of the Ryan White Comprehensive AIDS Resource Emergency Act. Section 2691(f) indicates that the Secretary may not make a grant under this program ''unless the applicant submits evidence that the proposed program is consistent with the Statewide Coordinated Statement of Need, and the applicant agrees to participate in the ongoing revision process of such statement of need.''

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The application may not exceed 40 double-spaced pages in length, excluding appendices. (The appendices are the appropriate location for curriculum vitae, references, letters of support, and memoranda of agreement documenting collaboration with other agencies.) Provide a one-page abstract of the proposal. Number all pages clearly and sequentially and include a complete table of contents to the application and its appendices. Submit the original and five copies of the application UNSTAPLED and UNBOUND. Print all material, double spaced, in a 12-point or larger font on 8½″ by 11″ paper, with at least 1″ margins and printed on one side only.

Use the following outline.

1. Experience With Relevant Research and Familiarity With HIV-Seropositive Injection Drug Users

a. Describe prior research and, if appropriate, service provision to IDUs, and particularly, HIV-seropositive IDUs. Describe methods used to collect prior data among IDUs regarding (1) HIV transmission risk and its correlates, AND (2) either access to, use of, and maintenance in health care, OR, access to, use of, and adherence to HIV treatments;

b. Demonstrate familiarity with issues faced by HIV-seropositive IDUs in coping with HIV, maintaining safer sex and injection practices, accessing and utilizing health care, and adhering to various HIV treatments such as antiretroviral treatment as well as medications used to prevent opportunistic infections. Applicant should describe both its own research experience with any of these issues as well as provide a review of the scientific literature.

c. Describe the characteristics of HIV-seropositive IDUs in the proposed study population, including demographic, drug taking, and other relevant characteristics;

d. Describe procedures for involving the target population, their advocates, or service providers in the design of research and intervention activities:

(1) A statement as to how the plans for recruitment and outreach for study participants include the process of establishing partnerships with communities; and

(2) The proposed plan for the inclusion of racial and ethnic minority populations and women for appropriate representation, and justification when representation is limited or absent.

2. Access to a Sufficient Number of HIV-Seropositive Injection Drug Users

a. Describe methods previously used to recruit and follow research samples of IDUs, particularly HIV seropositive IDUs, and document the ability to recruit and follow at least 200 HIV-seropositive injection drug users for the proposed research activities (including at least 100 IDUs newly diagnosed as HIV seropositive within the past three years).

b. Describe linkages and relationships with organizations providing medical and psycho social services to HIV-seropositive IDUs and how participants will be referred to these services as needed.

c. Demonstrate knowledge of the health care system available to the targeted population, specifically HIV outpatient medical care. Provide detail regarding ability to access care, ability to access HIV treatments, monitoring of adherence to medications, the process for appointment setting and follow-up, etc.

d. In the appendix, include a table of any intervention studies and prevention programs for HIV seropositive IDUs that you are conducting or that you are aware of in the proposed recruitment area. In this table, include target population; proposed activities; sites for recruitment, intervention, or data collection activities and provide a narrative describing potential overlap and plans to coordinate efforts (if any) to minimize overlap.

3. Intervention Research Plan

a. Propose an integrated behavioral/biomedical intervention that will

promote the three primary objectives: decreasing sexual and injection risk behavior, increasing access to and maintenance in primary health care, and increasing adherence to HIV treatments;

b. Describe the research design and methods that are proposed for the intervention. Include information about the research hypotheses, randomization procedures, primary (behavioral and biological) and secondary (relevant mediating variables) outcome measures, the reliability and validity of measures that will be used, and procedures for maximizing external and internal validity (e.g., sampling strategies and retention procedures, respectively);

c. Provide a detailed description of the proposed intervention and comparison conditions and give a rationale for each. Clearly specify the way in which the proposed intervention activities are based on findings from prior research and behavioral theory (include the intervention curriculum in the Appendix);

d. Propose a method for conducting a prospective cost analysis (excluding research costs) so the costs of the intervention will be available for replication purposes;

e. Describe procedures for obtaining informed consent and maintaining participant confidentiality;

f. Describe plans to develop specific documents necessary to replicate the intervention (if effective) and to disseminate study findings to community and scientific audiences.

4. Plan for Intervention Refinement and Piloting

Describe plans to refine and pilot the intervention to improve its acceptability to and feasibility with the target population;

5. Research and Intervention Capability

a. Describe the research team and organizational setting;

b. Describe the professional training and relevant research experience of all scientific staff;

c. Describe prior experience collecting biologic data (especially from IDUs) and conducting biomedical research in a behavioral context;

d. Include in the appendix memoranda of agreement that clearly and specifically document activities to be performed by any external agreements, consultants, or collaborating agencies under the cooperative agreement. Clearly indicate roles, responsibilities, and staffing provided by these collaborators.

6. Staffing, Facilities, and Time Line

a. Explain the proposed staffing, percentage of time each staff member commits to this and other projects, and division of duties and responsibilities for the project;

b. Describe the arrangements that you have made for facilitating access to primary health care for project participants;

c. Identify and describe key roles of behavioral scientists, biomedical scientists, and other staff essential to the completion of the project;

d. Describe support activities such as project oversight or data management that will contribute to the completion of all research activities;

e. Provide a statement that project staff will attend three or four meetings each year with CDC and HRSA staff and staff from other recipient sites;

f. Describe existing facilities (including ability to collect and store biologic data), equipment, computer software, and data processing capacity;

g. Describe the procedures to ensure the security of research data (including biologic data); and

h. Provide a time line for the completion of the proposed research.

7. Budget: Provide a Detailed, Line-Item Budget for the Project and a Budget Narrative That Justifies Each Line-Item.

F. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit.

On or before **August 6, 1999,** submit the application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Application shall be considered as meeting the deadline if they are either:

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 group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

If your application does not arrive in time for submission to the independent review group, it will not be considered in the current competition unless you can provide proof that you mailed it on or before the deadline (*i.e.*, receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Experience With Relevant Research and Familiarity With HIV-Seropositive Injection Drug Users (20 points)

a. Extent of applicant's knowledge of issues faced by HIV-seropositive IDUs, as demonstrated by prior research and review of the scientific literature, and applicant's experience in working with this population;

b. Evidence of: (1) Prior research on the correlates of sexual and injection risk behavior, and (2) research or research data on access to medical care, or adherence to HIV treatments among HIV-seropositive IDUs; and overall quality of research in all 3 areas;

c. Description of proposed study population and rationale for focusing on specific subgroups, if any;

d. Feasibility of plans to involve HIV-seropositive IDUs, their advocates, or service providers in the development of research and intervention activities.

2. Access to a Sufficient Number of HIV-Seropositive Injection Drug Users (20 points)

a. Quality of methods used to recruit and follow IDUs for prior studies, and particularly the quality of methods used to recruit HIV-seropositive IDUs and achieve high follow-up rates;

b. Evidence of ability to recruit at least 200 HIV-seropositive IDUs, including at least 100 newly diagnosed IDUs (diagnosed with HIV infection or AIDS in the past three years);

c. Existence of linkages to facilitate recruitment from and referral to programs providing services for HIV-seropositive IDUs;

d. Feasibility of proposed intervention given other intervention studies and prevention programs for HIV-seropositive IDUs being conducted by applicant or other investigators in the same greater metropolitan area;

3. Intervention Research Plan, and the Degree to Which the Applicant Has Met the CDC Policy Requirements Regarding the Inclusion of Ethnic and Racial Groups and Women in the Proposed Research (25 points)

a. Intervention Research Plan.

1. Quality, feasibility, and theoretical bases of the suggested biomedical/behavioral intervention;

2. Appropriateness of proposed research hypotheses and intervention outcome measures;

3. Quality and scientific rigor of the proposed research design and methods for the intervention trial;

4. Quality of the rationale for the curricula for the intervention and comparison conditions, including the extent to which intervention activities are based on findings from prior research and behavioral theory;

5. Ability to collect data for tracking costs (excluding research costs) to conduct a prospective cost analysis;

6. Adequacy of procedures for obtaining informed consent and maintaining participant confidentiality; and

7. Quality of plans to develop appropriate materials for intervention replication and to disseminate study findings to community and scientific audiences.

b. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of ethnic and racial groups and women in the proposed research.

1. The proposed plan for the inclusion of racial and ethnic minority populations and women for appropriate representation;

2. The proposed justification when representation is limited or absent;

3. A statement as to whether the design of the study is adequate to measure differences when warranted; and

4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

4. Plan for Intervention Refinement and Piloting (10 points)

Quality of the proposed plan to refine and pilot test the proposed intervention.

5. Research and Intervention Capability (20 points)

a. Ability of the applicant to conduct the proposed research as reflected in the training, research, and behavioral intervention experience of staff members;

b. Ability of the applicant to collect and monitor biologic data as reflected in prior experience;

c. Extent to which services to be provided by external experts, consultants, or collaborating agencies are documented by memoranda of agreement in the appendix, including a clear indication of roles, responsibilities, and staffing provided by these collaborators.

6. Staffing, Facilities, and Time Line (5 points)

a. Availability of qualified and experienced personnel with sufficient time dedicated to the proposed project. Presence of behavioral scientists in key leadership positions on the project;

b. Availability of persons with biomedical expertise on the research staff and among other project personnel to assure competent and appropriate collection and storage of biological specimens;

c. Clarity of the described duties and responsibilities of project personnel, including support personnel for project oversight and data management, as well as a clear plan for facilitating access to primary health care for participants;

d. Stated agreement to meet three or four times each year with CDC and HRSA staff and staff from other recipient sites to discuss and provide input to each site throughout the 5-year project;

e. Adequacy of the facilities (including ability to collect and store biologic data), equipment, data management resources, and systems for ensuring data security and;

f. Specificity and reasonableness of time line.

7. Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? (not scored)

8. Budget (not scored)

Extent to which the budget is reasonable, itemized, clearly justified, and consistent with the intended use of funds.

H. Other Requirements

1. Technical Reporting Requirements Provide CDC with original plus two copies of

a. semi-annual progress reports, no more than 30 days after the end of each reporting period. The progress reports must include the following for each program, function, or activity involved:

(1) A comparison of accomplishments of the goals established for the period;

(2) Reasons that any goals were not met and;

(3) A description of steps taken to overcome barriers to the goals for the period.

b. financial status report, no more than 90 days after the end of the budget period; and

c. final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

2. The following additional requirements are applicable to this program. For a complete description of each, see Attachments.

AR–1 Human Subjects Requirements
AR–2 Requirements for Inclusion of Racial and Ethnic Minorities in Research
AR–4 HIV/AIDS Confidentiality Provisions
AR–5 HIV Program Review Panel Requirements
AR–6 Patient Care
AR–9 Paperwork Reduction Act Requirements
AR–10 Smoke-Free Workplace Requirements
AR–11 Healthy People 2000
AR–12 Lobbying Restrictions

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317(k)(2), of the Public Health Service Act [42 U.S.C. 241 and 247b(k)(2)], as amended. The HRSA Special Projects of National Significance (SPNS) program is authorized by section 2691 of the Public Health Service Act (42 U.S.C.300ff–10). The Catalog of Federal Domestic Assistance number is 93.941.

J. Where To Obtain Additional Information

To receive additional written information and to request an application kit, call 1–888–GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. You may also view this and all other CDC/ATSDR competitive Program Announcements, and download application forms, via the Internet at http://www.cdc.gov.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Brenda Hayes, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Mail Stop E–15, Atlanta, GA 30341–4146, telephone: (770) 488–2720; Email: bkh4@cdc.gov.

Programmatic technical assistance may be obtained from: Robert Kohmescher, Centers for Disease Control and

Prevention (CDC), 1600 Clifton Road, NE, Mail Stop E–44, Atlanta, GA 30333, telephone (404) 639–1914 Email HTTP://WWW.RNK1.CDC.GOV
or
Jeff Efird, Centers for Disease Control and Prevention (CDC), 1600 Clifton Road, NE, Mail Stop E–45, Atlanta, GA 30333 telephone (404) 639–6136, Email HTTP://WWW.JLE1@cdc.gov

Dated: June 15, 1999.

Henry S. Cassell III,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–15632 Filed 6–18–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0790]

EM Industries, Inc.; Filing of Color Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a color additive petition filed by EM Industries, Inc., to clarify that the petitioner's request is to amend the color additive regulations to provide for the safe use of composite pigments made from synthetic iron oxide, titanium dioxide, and mica to color food.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 25, 1998 (63 FR 51359), FDA announced that a color additive petition (CAP 8C0262) had been filed by EM Industries, Inc., 7 Skyline Dr., Hawthorne, NY 10532. The petition proposed to amend the color additive regulations to provide for the safe use of synthetic iron oxide and mica to color food and to provide for the safe use of titanium dioxide to color food at levels higher than the current limit.

The data in the petition indicated that the petitioner manufactured color additives, to color food, by combining synthetic iron oxide, mica, and titanium dioxide. Based on these data, at the time of the filing of the petition, FDA considered the color additive combinations the petitioner prepared from synthetic iron oxide, mica, and titanium dioxide to be color additive mixtures.

To more accurately describe the pigments that are the subjects of this petition, FDA is amending the filing notice of September 25, 1998, to indicate that the petition proposes to amend the color additive regulations to provide for the safe use of composite pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color food.

The agency has determined under 21 CFR 25.32(r) 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 2, 1999.

Alan M. Rulis,

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

[FR Doc. 99–15661 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F–1867]

Asahi Chemical Industry Co. and Japan Synthetic Rubber Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Asahi Chemical Industry Co. and Japan Synthetic Rubber Co. have filed a petition proposing that the food additive regulations be amended to provide for the safe use of 2,4-diphenyl-4-methyl-1-pentene (common name alpha-methylstyrene dimer) in the manufacture of coatings for food-contact paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

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 9B4666) has been filed by Asahi Chemical Industry Co. and Japan Synthetic Rubber Co., c/o Environ International Corp., 4350 North Fairfax Dr., suite 300, Arlington, VA 22203. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of 2,4-diphenyl-4-methyl-1-pentene (common name alpha-methylstyrene dimer) in the manufacture of coatings for food-contact paper and paperboard.

The agency has determined under 21 CFR 25.32(i) 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 2, 1999.

Alan M. Rulis,

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

[FR Doc. 99–15662 Filed 6–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–1833]

SoloPak Laboratories, Inc.; Withdrawal of Approval of 1 New Drug Application and 38 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 1 new drug application (NDA) and 38 abbreviated new drug applications (ANDA's). SoloPak Laboratories, Inc., notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: July 21, 1999.

FOR FURTHER INFORMATION CONTACT: Olivia A. Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: SoloPak Laboratories, Inc., 1845 Tonne Rd., Elk Grove Village, IL 60007–5125, has informed FDA that the drug products listed in the following table are no longer marketed and has requested that FDA withdraw approval of the applications. SoloPak Laboratories, Inc.,