between individuals having the same or similar names.

RECORD ACCESS PROCEDURES:

Individuals may have access to their records by making a written request, addressed to the System Manager specified above. The envelope containing the written request must be marked ''Privacy Act Request'' or ''Freedom of Information Act Request'' or both, in the bottom left-hand corner. The letter requesting access to FCR records must state the following: (1) That the request is being made under the Privacy Act; Freedom of Information Act, or both, (2) the name, address, and signature of the requester; and (3) a detailed description of the record contents they are seeking.

CONTESTING RECORD PROCEDURE:

Individuals may request an amendment of a record which is not accurate, relevant, timely, or complete by writing to the System Manager at the address specified above. The envelope containing the written request must be marked ''Privacy Act Amendment Request'' or ''Freedom of Information Act Request'' or both, in the bottom left-hand corner. The letter requesting an amendment to FCR records must state the following: (1) That the request to amend the record is being made under the Privacy Act; Freedom of Information Act, or both, (2) the individual's name, address, and signature; (3) a description of the contested information; (4) the reason why the information should be amended; and (5) documentation to show that the information is inaccurate, irrelevant, untimely, or incomplete. Individuals who are contesting records must also be able to prove their identity.

RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State.

SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 98–22581 Filed 8–21–98; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0676]

Warner-Jenkinson Co., Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Warner-Jenkinson Co., Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3167.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1)), notice is given that a color additive petition (CAP 8C0261) has been filed by Warner-Jenkinson Co., Inc., 107 Wade Ave., South Plainfield, NJ 07080. The petition proposes to amend the color additive regulations to provide for the safe use of External D&C Violet No. 2 in coloring externally applied drug products.

The agency has determined under 21 CFR 25.32(l) 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: July 28, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–22569 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–0675]

The Dow 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 The Dow Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyethylenepolyamines as cross-linking agents for epoxy resins in coatings intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3086.

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 8B4606) has been filed by The Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposes to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of polyethylenepolyamines as cross-linking agents for epoxy resins in coatings intended for use in contact with food.

The agency has determined under 21 CFR 25.32(j) that this action is of the type that does not individually or cumulatively have a significant effect on the environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 28, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–22570 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Arthritis Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 16, 1998, 8 a.m. to 5 p.m.

Location: Gaithersburg Holiday Inn, Walker and Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Gail M. Dapolito or Bill Freas, Center for Biologics Evaluation and Research (HFM–21),

Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1289, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application 98–0286, Enbrel™ (etanercept, Immunex) for the treatment of rheumatoid arthritis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 10, 1998. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 10, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 11, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–22572 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 17, 1998, 8 a.m. to 6 p.m., and September 18, 1998, 8 a.m. to 3:30 p.m.

Location: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD.

Contact Person: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 17, 1998, the committee will hear: (1) Updates on HCV nucleic acid testing; (2) year 2000 computer software; (3) recent review of albumin clinical trials; (4) informational summaries on the Hematopoietic/Progenitor Cell Products Workshop, Granulocytes for Transfusion Workshop, Nucleic Acid Testing for HCV and Other Viruses in Blood Donors Workshop; and (5) an informational presentation on TT virus and transfusion safety. In the afternoon, the committee will discuss and make recommendations on the Abbott Laboratories PRISM Detection Assay for HBsAg, Anti-HCV, and Anti-HTLV-I/II. On September 18, 1998, the committee will discuss and make recommendations on the topic of routine leukoreduction of blood components.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 1998. On September 17, 1998, oral presentations from the public will be scheduled between approximately 3:30 p.m. and 4 p.m. and on September 18, 1998, between approximately 11:15 a.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–22566 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Gas; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) (Nashville District Office) is announcing the following public workshop: Medical Gas Workshop. The topics to be discussed are current good manufacturing practice issues for the medical gas industry, including air liquefaction, transfilling, and hospital installations.

Date and Time: The public workshop will be held on Tuesday, October 27, 1998, 8 a.m. to 4:30 p.m.

Location: The public workshop will be held at the Holiday Inn Select, Nashville Opryland/Airport, 2200 Elm Hill Pike, Nashville, TN 37214. Maps to the public workshop location will be faxed upon request.

Contact: Kari L. Norton, Food and Drug Administration, 297 Plus Park Blvd., Nashville, TN 37217, 615–781–5380, ext. 112, FAX 615–781–5391, or e-mail ''knorton@ora.fda.gov''.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, October 2, 1998. Please include ''Medical Gas Workshop Registration'' in the subject line. There is no registration fee for this public workshop. Space is limited to 150 registrants, and further limited to 2 attendees per firm. Firms desiring more than two slots may be accommodated if there are vacancies.

If you need special accommodations due to a disability, please contact Kari L. Norton at least 7 days in advance.

Dated: August 11, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–22567 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F