

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-19894 Filed 7-24-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F-0568]

FMC Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that FMC Corp., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3072.

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 8A4605) has been filed by FMC Corp., c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 172.846 (21 CFR 172.846) to provide for the expanded safe use of sodium stearoyl lactylate as an emulsifier, stabilizer, and texturizer in salad dressings and soups. The agency has determined under 21 CFR 25.32(k) 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 6, 1998.

Laura M. Tarantino,

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

[FR Doc. 98-19893 Filed 7-24-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Granulocytes for Transfusion: Research and Clinical Experience; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Granulocytes for Transfusion: Research and Clinical Experience. This workshop, which is cosponsored by FDA and the National Institutes of Health (NIH), will include a discussion of the effects of cytokine administration on normal donors, the functional properties of the transfusion product, the effects of storage conditions on the product, and the safety and effectiveness of the product.

Date and Time: The public workshop will be held on Friday, September 11, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number) and written material and requests to make oral presentations to the contact person by Wednesday, August 12, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The findings that administration of Granulocyte-Colony Stimulating Factor or Granulocyte-Macrophage Colony Stimulating Factor to normal volunteers results in the peripheral mobilization of high

concentrations of granulocytes has renewed an interest in the collection of granulocytes for transfusion. The goals of the workshop are to discuss: (1) The current scientific and clinical experience with cytokine mobilized granulocyte transfusion products; (2) the effects of cytokine administration on normal donors; (3) the functional properties of transfusion product; and (4) studies needed to establish the safety and effectiveness of the transfusion product. The information obtained from these presentations will assist FDA in assessing the safety and effectiveness of the product and will assist NIH in identifying areas in need of further research.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-19955 Filed 7-24-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Evaluation of In Vivo Efficacy of Platelet Transfusion Products and Platelet Substitutes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Evaluation of In Vivo Efficacy of Platelets and Platelet Substitutes. This workshop is cosponsored by FDA, the United States Army, and the National Institutes of Health. The topics to be discussed include: Current methodology for efficacy assessment of transfused platelets; definition of efficacy for platelet substitutes; animal models of platelet efficacy; discussion of the therapeutic "cost versus benefit" of using platelets treated with novel decontamination treatments or stored with novel media/methods, or of using platelet substitutes.

Date and Time: The public workshop will be held on Monday, September 28, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at Wilson Hall, Bldg. 1, National

Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM-350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6129, FAX 301-827-2843.

Registration and Request for Oral Presentations: Mail or fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by August 28, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop. Requests for oral presentations should be sent to Jaroslav G. Vostal, Division of Hematology (HFM-335), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-496-2577, FAX 301-402-2780, e-mail "VOSTAL@A1.CBER.FDA.GOV". Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The goals of the workshop include the following: (1) Review current methodology for measuring platelet clinical efficacy; (2) define the clinical efficacy of a platelet transfusion; (3) discuss similarities and differences between intact platelets and platelet substitutes; (4) present animal models used for measuring platelet substitute efficacy; and (5) discuss design of clinical trials to establish clinical efficacy for platelets and platelet substitutes. The information obtained from these presentations will assist FDA in developing standards to evaluate novel platelet products and to assure the safety and effectiveness of these products. *Transcripts:* Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-19896 Filed 7-24-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0497]

Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop: Hematopoietic Stem/Progenitor Cell Products: Discussion of Unrelated Allogeneic Placental/Umbilical Cord Blood and Peripheral Blood Cell Banking and Transplantation. This workshop, which is cosponsored by FDA and the National Institutes of Health, will include a discussion of the current status of clinical and nonclinical laboratory data to support the development of standards for unrelated allogeneic peripheral and placental/umbilical cord blood hematopoietic stem/progenitor cell products; studies to obtain data for product safety and effectiveness; and the notice and request for comments entitled "Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products: Request for Comments" that published in the **Federal Register** of January 20, 1998 (63 FR 2985).

Date and Time: The public workshop will be held on Thursday, September 10, 1998, 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD.

Contact Person: Joseph Wilczek, Food and Drug Administration, Center for Biologics Evaluation and Research (HFM-350), 1401 Rockville Pike, Rockville, MD 20852, 301-827-6129, FAX 301-827-2843.

SUPPLEMENTARY INFORMATION: The goals of this workshop are to: (1) Discuss the current status of related and unrelated allogeneic peripheral blood hematopoietic stem/progenitor cell collection; (2) discuss the current status of unrelated allogeneic placental/umbilical cord blood banking and transplantation; (3) discuss issues regarding the administration of cytokines to normal donors for the mobilization of peripheral blood

hematopoietic stem/progenitor cells and transplantation; and (4) address questions the public may have regarding the notice and request for comments published in the **Federal Register** of January 20, 1998 (63 FR 2985). The information obtained from these presentations will assist FDA and the interested public in developing standards for unrelated allogeneic peripheral blood and placental/umbilical cord blood hematopoietic stem/progenitor cell products.

Registration and Requests for Oral Presentations: Send or fax registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations, to the contact person by Tuesday, August 11, 1998. Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for this workshop.

If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0049]

Guidance for Industry on Environmental Assessment of Human Drug and Biologics Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Environmental Assessment of Human Drug and Biologics Applications." This guidance is intended to provide information on when an environmental assessment (EA) should be submitted in support of a human drug or biologics application