

"Demonstration and Evaluation of State Family Reunification Efforts" and (3) "Demonstration and Evaluation of State Termination of Parental Rights Efforts." Papers are due on the 15th of January. The papers will be reviewed by a panel and final selections will be made by the Commissioner of the Administration on Children, Youth and Families. The top five applicants will be invited to participate in the meeting. Travel expenses and honoraria will be paid.

**MATTERS TO BE CONSIDERED:** At this meeting the Administration on Children, Youth and Families will lead a discussion to explore new and innovative interventions and evaluation designs on the topics listed above, which could be used to improve and evaluate State Child Welfare Services Systems. The meeting will focus on the content of the five papers selected from those submitted. These papers will cover proposed demonstrations and their companion evaluation plans for three topics: (1) "State Family Preservation Efforts", (2) "State Family Reunification Efforts" and (3) "State Termination of Parental Rights Efforts." Participants whose papers are selected will present their papers, and participate in open-ended discussions with a review board of Federal experts in the field of Child Welfare. Each paper should be in the form of a synopsis and should be typed double-spaced on a single-side of an 8½" x 11" plain white paper with 1" margins on all sides. The length of the application synopsis should not exceed 10 pages. Application synopses will be reviewed by a panel of at least three reviewers, primarily experts within the Federal Government, using the three criteria outlined below.

**1. Approach to the Demonstration (40 points)**

The extent to which the application outlines an original and practical plan for the subject area selected; provides supporting documentation; identifies the potential barriers to the proposed innovation, giving acceptable reasons for taking this approach as opposed to others; and discusses a reasonable schedule of accomplishments and targets for the reforms.

**2. Approach to the Evaluation (40 points)**

The extent to which the application outlines a sound and workable evaluation plan for the subject area selected; identifies the kinds of data to be collected and maintained; and discusses the criteria to be used to evaluate the results of any proposed reforms.

**3. Staff Background and Organization's Experience (20 points)**

The extent to which the application describes the background of the principal investigator and key staff (including name, address, training, educational background and other relevant experience) and the relevance and adequacy of their experience and the experience of their organization in conducting large scale evaluation efforts.

Once selected, the five presenters will be expected to develop their topic more fully (30 pages) for presentation at the meeting. The experts that will comprise the review board will give significant comment and guidance to the presenters. The Administration on Children, Youth and Families plans to use the documents prepared for this meeting, along with the comments of the review panel, to prepare an issuance to stimulate States to submit innovative approaches to conduct demonstrations to improve their Child Welfare Systems.

It should be noted that this call for papers is not a solicitation for a grant and no monies will be awarded to any applicant resulting from this announcement. However, presenters selected for this meeting may be at a competitive advantage, due to the review panel comments and guidance received, when organizations are selected to evaluate State Child Welfare Systems.

**CONTACT PERSON FOR MORE**

**INFORMATION:** Mrs. Margaret Baker, Commissioner's Office, Administration on Children, Youth and Families, 330 C Street, SW, room 2026, Switzer Building, Washington, DC 20201, (202) 245-0347.

Dated: November 15, 1991.

Wade F. Horn, Ph.D.,  
Commissioner, Administration on Children,  
Youth and Families.

[FR Doc. 91-28551 Filed 11-27-91; 8:45 am]

BILLING CODE 4130-01-M

**Food and Drug Administration**

**Ivermectin Injection in Foxes;  
Availability of Data**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of target animal safety and effectiveness data to be used in support of a new animal drug application (NADA) or supplemental NADA for the use of ivermectin injection in foxes. The data, contained in Public Master File

(PMF) 5307, were compiled under Interregional Research Project No. 4 (IR-4), a national agricultural program for obtaining clearances for use of agricultural products for minor special uses.

**ADDRESSES:** Submit NADA's or supplemental NADA's to the Document Control Unit (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8659.

**SUPPLEMENTARY INFORMATION:**

Ivermectin injection for use in foxes is a new animal drug under section 201(w) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(w)). As a new animal drug, ivermectin is subject to section 512 of the act (21 U.S.C. 360(b)) requiring that its use in foxes be the subject of an approved NADA or supplemental NADA. Foxes are a minor species under 21 CFR 514.1(d). The IR-4 Project, Northcentral Region, Michigan State University, East Lansing, MI 48824, has provided data and information demonstrating safety and effectiveness in ranch-raised foxes for subcutaneous use of ivermectin injection for the control of ear mites (*Otodectes cynotis*).

The data and information are contained in PMF 5307. Sponsors of NADA's or supplemental NADA's may, without further authorization, reference the PMF to support approval under 21 CFR 514.1(d). An NADA or supplemental NADA must include, in addition to a reference to the PMF, animal drug labeling and other information needed for approval, such as manufacturing methods, facilities and controls, and information addressing the potential environmental impacts (including occupational) of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Naba K. Das (address above).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information in this PMF submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. to 4 p.m., Monday through Friday.

Dated: October 21, 1991.

Gerald B. Guest,

Director, Center for Veterinary Medicine,

[FR Doc. 91-28607 Filed 11-27-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0413]

**Eastman 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 Eastman Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of 1-hexene as a monomer for polymer resins used as adhesives for articles or components of articles that contact food.

**FOR FURTHER INFORMATION CONTACT:** Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 1B4292) has been filed by Eastman Chemical Co., P.O. Box 511, Kingsport, TN 37662. The petition proposes to amend the food additive regulations in § 175.105 Adhesives (21 CFR 175.105) to provide for the safe use of 1-hexene as a monomer for polymer resins used as adhesives for articles or components of articles that contact 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: November 18, 1991.

Douglas L. Archer,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-28605 Filed 11-27-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0423]

**ICI Americas, Inc.; Filing of Food Additive Petition**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that ICI Americas, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of *N,N*-bis(2-hydroxyethyl)alkyl(C<sub>13</sub>-C<sub>15</sub>)amine as an antistatic agent in the manufacture of olefin polymer articles intended to contact food.

**FOR FURTHER INFORMATION CONTACT:** Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), 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. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B4297) has been filed by ICI Americas, Inc., Concord Pike and Murphy Rd., Wilmington, DE 19897. The petition proposes to amend the food additive regulations in § 178.3130 *Antistatic and/or antifogging agents in food-packaging materials* (21 CFR 178.3130) to provide for the safe use of *N,N*-bis(2-hydroxyethyl)alkyl(C<sub>13</sub>-C<sub>15</sub>)amine as an antistatic agent in the manufacture of olefin polymer articles intended to contact 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: November 18, 1991.

Douglas L. Archer,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-28602 Filed 11-27-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91F-0424]

**Sherex Chemical Co., Inc.; Filing of Food Additive Petition**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that Sherex Chemical Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of imidazolium compounds, 2-(C<sub>17</sub> and C<sub>18</sub> unsaturated alkyl)-1-[2-C<sub>13</sub> and C<sub>18</sub> unsaturated

amido) ethyl]-4, 5-dihydro-1-methyl, methyl sulfates as a wet strength agent in paper products intended to contact food.

**FOR FURTHER INFORMATION CONTACT:** Vir Anand, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 1B4282) has been filed by Serex Chemical Co., Inc., P.O. Box 6464, Dublin, OH 43017. The petition proposes to amend the food additive regulations to provide for the safe use of imidazolium compounds, 2-(C<sub>17</sub> and C<sub>18</sub> unsaturated alkyl)-1-[2-C<sub>13</sub> and C<sub>18</sub> unsaturated amido) ethyl]-4, 5-dihydro-1-methyl, methyl sulfates as a wet strength agent in paper products intended to contact 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: November 18, 1991.

Douglas L. Archer,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 91-28606 Filed 11-27-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91N-0428]

**Draft of "Points To Consider in Human Somatic Cell Therapy and Gene Therapy;" Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft points to consider (PTC) document entitled "Points to Consider in Human Somatic Cell Therapy and Gene Therapy." The draft PTC document is intended for manufacturers, sponsors, and investigators of human somatic cell therapy and gene therapy products. The draft PTC document discusses topics that should be considered in the development of such products.

**DATES:** Submit written comments on the draft PTC by January 28, 1992.

**ADDRESSES:** Submit written requests for single copies of the draft PTC to the Congressional, Consumer, and International Affairs Branch (HFB-142), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, except that written requests delivered by carriers other than the U.S. Postal Service should be submitted to the Congressional, Consumer, and International Affairs Branch (HFB-142, Food and Drug Administration, suite 109, Metro Park North 3, 7564 Standish Pl., Rockville, MD 20855. Send two self-addressed, adhesive labels to assist that office in processing your requests. Submit written comments on the draft PTC document to the Dockets Management Branch (HFA-305), Food and Drug Administration, room 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Copies of the draft PTC document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Ann Reed Gaines, Center for Biologics Evaluation and Research (HFB-132), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301-295-8188.

**SUPPLEMENTARY INFORMATION:** Human somatic cell therapy is the administration of autologous, allogeneic, or xenogeneic living cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise biologically altered. The cells are processed or modified *ex vivo*; however, the therapeutic, diagnostic, or preventive effect of somatic cell therapy products is exerted *in vivo*. Examples of human somatic cell therapy products currently under investigation include lymphokine-activated killer cells, used to destroy tumor tissue in the treatment of cancer, and encapsulated pancreatic islet cells, used to supply insulin in the treatment of diabetes.

Human gene therapy involves the modification of the genetic material of living cells. Cells may be modified either *ex vivo* or *in vivo*; however, the therapeutic or prophylactic effect of human gene therapy products is exerted *in vivo*. An example of a human gene therapy product currently under investigation is a product for the treatment of adenosine deaminase (ADA) deficiency, in which the ADA enzyme, necessary for the normal functioning of the immune system, is lacking. The gene therapy product being investigated consists of cells that have

been genetically modified to produce ADA.

FDA has determined that current issues to be considered in the development of human somatic cell therapy or gene therapy products should be summarized and made available to manufacturers, investigators, and sponsors. FDA is thus announcing the availability of a draft entitled "Points to Consider in Human Somatic Cell Therapy and Gene Therapy." The draft PTC was prepared by the Center for Biologics Evaluation and Research, FDA, and is dated August 1991. The draft PTC is intended to facilitate development of human somatic cell therapy and gene therapy products by providing guidance on various biological, clinical, and manufacturing topics specific to these products. Among the topics discussed in the draft PTC are characterization of cell populations, preclinical safety testing, lot-to-lot manufacturing control testing, and clinical trial considerations.

As with other PTC documents, FDA does not intend this draft PTC document to be all-inclusive and cautions that not all information may be applicable to all situations. The draft PTC document is intended to provide information and does not set forth requirements. The methods and procedures cited in the draft PTC document are suggestions; FDA anticipates that manufacturers, investigators, and sponsors may develop alternative methods and procedures. FDA further anticipates revising the draft PTC periodically, in response to comments received or to reflect advancements in somatic cell and gene therapies and products. Comments on this draft will be on file in the Dockets Management Branch under the docket number found in brackets in the heading of this document.

Dated: November 22, 1991.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 91-28604 Filed 11-27-91; 8:45 am]

BILLING CODE 4160-01-M

## Health Care Financing Administration

[BPO-95-GNC]

### Medicare Program; Standard Claim Forms for Part B Claims Completed and Submitted by Physicians, Suppliers and Other Persons

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

**ACTION:** General notice with comment period.

**SUMMARY:** This notice announces that effective April 1, 1992, Medicare carriers will no longer accept nonstandard claims. These are claims accompanied by attachments, in lieu of the biller entering required information in designated blocks of prescribed claims forms. This change is intended to eliminate costly and inefficient claims processing practices for Medicare carriers.

**DATES:** The provisions of this notice are effective for claims submitted on or after April 1, 1992.

**COMMENT PERIOD:** Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 pm. on January 28, 1992.

**ADDRESS:** Address comments in writing to: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO-95-GNC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your written comments to one of the following locations:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC. 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resources limitations, we cannot accept audio, visual or facsimile (FAX) copies of comments. In commenting, please refer to BPO-95-GNC.

Written comments will be available for public inspections as they are received, beginning approximately three weeks after publication, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC. 20201, on Monday through Friday of each week from 8:30 am. to 5 p.m. (phone: (202) 245-7890).

**FOR FURTHER INFORMATION CONTACT:** Max Buffington, (301) 966-6968.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The Medicare Supplementary Medical Insurance (SMI) program is the voluntary Medicare Part B program that pays all or part of the costs for physicians' services, outpatient hospital services, home health services, services furnished by rural health clinics, ambulatory surgical centers, and comprehensive outpatient rehabilitation facilities, and certain other medical and other health services not covered by hospital insurance (Medicare Part A). The SMI program is available, upon payment of a premium, to individuals