approval according to the prescribed content and format.

• 21 CFR 208.24(e)—Each authorized dispenser of a prescription drug product for which a Medication Guide is required, when dispensing the product to a patient or to a patient's agent, must provide a Medication Guide directly to each patient unless an exemption applies under § 208.26 (21 CFR 208.26).

• Section 208.26(a)—Requests may be submitted for exemption or deferral from particular Medication Guide content or format requirements.

• 21 CFR 314.70(b)(3)(ii) and 21 CFR 601.12(f)—Application holders must submit changes to Medication Guides to FDA for prior approval as supplements to their applications.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
208.20	10	1	10	320	3,200
208.24(e)	59,000	5,000	295 million	.0014	413,000
208.26(a)	1	1	1	4	4
314.70(b)(3)(ii) and 601.12(f)	5	1	5	72	360
Total					416,564

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

Dated: March 11, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–5384 Filed 3–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007F–0478]

Kemira Oyj; Filing of Food Additive Petition (Animal Use); Partially Ammoniated Formic Acid; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document announcing the filing of a food additive petition that appeared in the **Federal Register** of January 11, 2008. FDA is correcting the name of the petitioner which was misspelled during document drafting.

DATES: This correction is effective March 18, 2008.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–267–9019, e-mail: *george.haibel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–316, published on January 11, 2008 (73 FR 2055), the following correction is made:

On page 2055, in the second column, in the **SUMMARY** and **SUPPLEMENTARY INFORMATION** sections, ''Oyi'' is corrected to read ''Oyj''.

Dated: March 7, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–5453 Filed 3–17–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Committee on Organ Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the fourteenth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on May 5, 2008, and from 9 a.m. to 3 p.m. on May 6, 2008, at the Hilton Washington D.C./Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations on the ''Kidney Disease Outcome Quality Initiative/Early Kidney Transplantation Conference'' held on March 19–20, 2007; adolescent/medication nonadherence/transitioning from pediatric-adolescent care to adult care; revised informed consent recommendation; recovery/allocation/transplantation practices outside the United States; and a final report on the economics of transplantation. The four ACOT work groups also will update the

full Committee on their deliberations on informed consent, sources of funding for additional data collection, reducing pediatric deaths on the waitlist, and xenotransplantation.

The draft meeting agenda will be available on April 21 on the Department's donation Web site at *http://www.organdonor.gov/acot.html*.

A registration form will be available on April 7 on the Department's donation Web site at *http://www.organdonor.gov/acot.html*. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Individuals without access to the Internet who wish to register may call Amanda Madeline with PSA at (703) 234–1244. Registration can also be completed electronically at *http://www.psava.com/dot/acot2008/*. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Secretary, Gregory Fant, Ph.D., in advance of the meeting. Dr. Fant may be reached by telephone at 301–443–8728, e-mail: *Gregory.Fant@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: March 12, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–5460 Filed 3–17–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the second meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on April 28, 2008, and from 9 a.m. to 3 p.m. on April 29, 2008, at the Hilton Washington D.C./Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 109–129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended) the ACBSCT was established to advise the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program. ACBSCT is composed of up to 25 members, including the Chair, serving as Special Government Employees. The current membership includes representatives of marrow donor centers and marrow transplant centers; representatives of cord blood banks and participating birthing hospitals; recipients of a bone marrow transplant; recipients of a cord blood transplant; persons who require such transplants; family members of such a recipient or family members of a patient who has requested the assistance of the Program in searching for an unrelated donor of bone marrow or cord blood; persons with expertise in bone marrow and cord blood transplantation; persons with expertise in typing, matching, and transplant outcome data analysis; persons with expertise in the social sciences; basic scientists with expertise in the biology of adult stem cells; ethicists; hematology and transfusion medicine researchers with expertise in adult blood stem cells; persons with expertise in cord blood processing; and members of the general public.

The Council will hear reports from five of the ACBSCT Work Groups: Cord Blood Accreditation Organization and Recognition Process, Need for Public Funding for Required Data Documentation, Process for Access of Cord Blood Units for Research, Scientific Factors Necessary to Define a Cord Blood Unit as High Quality, and Program Confidentiality/Policies for Cord Blood Donors.

The draft meeting agenda will be available on April 15, 2008, on the HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html*.

A registration form will be available on April 1, 2008, on the HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html*. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Registration can also be completed electronically at *https://www.team-psa.com/dot/2008/acbsct/*. Individuals without access to the Internet who wish to register may call Amanda Madeline with PSA at (703) 234–1244.

Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACBSCT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3264, e-mail: *Remy.Aronoff@hrsa.hhs.gov* or in writing at the address provided below. Management and support services for ACBSCT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be made available on the HRSA's Program Web site at *http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html*.

Dated: March 12, 2008.

Elizabeth M. Duke,

Administrator.

[FR Doc. E8–5461 Filed 3–17–08; 8:45 am]

BILLING CODE 4165–15–P