

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<sup>1</sup>

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

**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, “Oyj” 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]

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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

**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](mailto:george.haibel@fda.hhs.gov).

**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