

there certain applications for which an ingredient (inactive or active) must be derived from one of these grains for reasons related to physical properties, performance characteristics, safety, efficacy, availability, or reformulation burden, as well as other reasons?

C. Exposure Estimate

7. Is it possible to determine, with a high level of assurance, that certain drug ingredients derived from wheat, barley, or rye are free of gluten or would contribute only very dilute, insignificant, and nonharmful quantities of gluten to a drug product? If so, what scientific evidence supports such a determination?

D. Routes of Administration

8. FDA believes that the use of ingredients derived from wheat, barley, or rye in drugs administered orally presents a particular risk to individuals who have celiac disease, as compared to use of these ingredients in drugs dispensed in dosage forms intended for other routes of administration. FDA welcomes comments in this area. Are ingredients derived from wheat, barley, or rye presently used in drugs that are intended for nonoral routes of administration, such as topical, injectable, or ano-rectally administered drugs? Please submit any data or information on risks to celiac patients associated with nonoral exposure to ingredients derived from wheat, barley, or rye.

E. Incidental Addition of Gluten

9. FDA is primarily interested in ingredients derived from wheat, barley, or rye that are intentionally added to and intended to remain in the drug product. However, the Agency welcomes responses to the following question: Are processing aids or production aids (e.g., filtration media or fermentation media) derived from wheat, barley, or rye used today that could introduce gluten into a drug product at nontrivial levels?

IV. Submission of Information and Comments

Interested persons may submit information and comments responsive to this request to the Division of Dockets Management (see **ADDRESSES**) in electronic or written form. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, submissions may be

seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and on the Internet at <http://www.regulations.gov>.

V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Fasano, A., and C. Catassi, "Current Approaches to Diagnosis and Treatment of Celiac Disease: An Evolving Spectrum," *Gastroenterology*, vol. 120, pp. 636-651, 2001.
2. National Institutes of Health (NIH), "NIH Consensus Development Conference Statement on Celiac Disease, June 28-30, 2004," *Gastroenterology*, vol. 128, pp. S1-S9, 2005.
3. Jabri, B., D.D. Kasarda, and P.H.R. Green, "Innate and Adaptive Immunity: The Yin and Yang of Celiac Disease," *Immunological Reviews*, vol. 206, pp. 219-231, 2005.
4. Molberg, O., N.S. Flaete, T. Jensen, *et al.*, "Intestinal T-Cell Responses to High-Molecular-Weight Glutenins in Celiac Disease," *Gastroenterology*, vol. 125, pp. 337-344, 2003.
5. Farrell, R.J. and C.P. Kelly, "Celiac Sprue," *The New England Journal of Medicine*, vol. 346, pp. 180-188, 2002.
6. Fasano, A., I. Berti, T. Gerarduzzi, *et al.*, "Prevalence of Celiac Disease in At-Risk and Not-At-Risk Groups in the United States: A Large Multicenter Study," *Archives of Internal Medicine*, vol. 163, pp. 286-292, 2003.
7. West, J., R.F.A. Logan, P.G. Hill, *et al.*, "Seroprevalence, Correlates, and Characteristics of Undetected Coeliac Disease in England," *Gut*, vol. 52, pp. 960-965, 2003.
8. Green, P.H.R. and B. Jabri, "Coeliac Disease," *Lancet*, vol. 362, pp. 383-391, 2003.
9. Rubio-Tapia, A., R.A. Kyle, E.L. Kaplan, *et al.*, "Increased Prevalence and Mortality in Undiagnosed Celiac Disease," *Gastroenterology*, vol. 137, pp. 88-93, 2009.
10. Catassi, C., I. Bearzo, and G.K.T. Holmes, "Association of Celiac Disease and Intestinal Lymphomas and Other Cancers," *Gastroenterology*, vol. 128, pp. S79-S86, 2005.
11. Corrao, G., G.R. Corazza, V. Bagnardi, *et al.*, "Mortality in Patients With Coeliac Disease and Their Relatives: A Cohort Study," *Lancet*, vol. 358, pp. 356-361, 2001.
12. Waga, J., "Structure and Allergenicity of Wheat Gluten Proteins—A Review," *Polish Journal of Food and Nutrition Sciences*, vol. 13, pp. 327-338, 2004.
13. Vader, W., Y. Kooy, P. Van Veelen, *et al.*, "The Gluten Response in Children With Celiac Disease Is Directed Toward Multiple Gliadin and Glutenin Peptides," *Gastroenterology*, vol. 122, pp. 1729-1737, 2002.
14. Kieffer, M., P.J. Frazier, N.W.R. Daniels, *et*

- al.*, "Wheat Gliadin Fractions and Other Cereal Antigens Reactive With Antibodies in the Sera of Coeliac Patients," *Clinical and Experimental Immunology*, vol. 50, pp. 651-660, 1982.
15. Sturgess, R.P., H.J. Ellis, and P.J. Ciclitira, "Cereal Chemistry, Molecular Biology, and Toxicity in Coeliac Disease," *Gut*, vol. 32, pp. 1055-1060, 1991.
16. Lundin, K.E.A., E.M. Nilsen, H.G. Scott, *et al.*, "Oats Induced Villous Atrophy in Coeliac Disease," *Gut*, vol. 52, pp. 1649-1652, 2003.
17. Janatuinen, E.K., T.A. Kempainen, R.J.K. Julkunen, *et al.*, "No Harm From Five Year Ingestion of Oats in Coeliac Disease," *Gut*, vol. 50, pp. 332-335, 2002.
18. Haboubi, N.Y., S. Taylor, and S. Jones, "Coeliac Disease and Oats: A Systematic Review," *Postgraduate Medicine Journal*, vol. 82, pp. 672-678, 2006.
19. Office of Food Safety, Center for Food Safety and Applied Nutrition, Food and Drug Administration, "Health Hazard Assessment for Gluten Exposure in Individuals With Celiac Disease: Determination of Tolerable Daily Intake Levels and Levels of Concern for Gluten," May 2011.
20. Citizen Petition submitted by Michael Weber, June 2008, Docket No. FDA-2008-P-0333.

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32551 Filed 12-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0381]

Generic Drug User Fee; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Thursday, December 8, 2011 (76 FR 76738). The document announced a public meeting entitled "Generic Drug User Fee." The document published with an inadvertent error in the **DATES** section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993-0002, (301) 796-9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011-31630, appearing on page 76738

in the **Federal Register** of Thursday, December 8, 2011, the following correction is made:

On page 76738, in the third column, under the **DATES** section, "January 6, 2011" is corrected to read "January 6, 2012".

Dated: December 15, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-32562 Filed 12-20-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: January 13, 2012.

Time: 8:30 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Camilla E. Day, Ph.D., Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, (301) 402-8837, camilla.day@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: December 14, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-32705 Filed 12-20-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Peer Review Meeting.

Date: January 9, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892-7616, (301) 594-1009, fdesilva@niaid.nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, Systems Approach to Immunity and Inflammation.

Date: January 12-13, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Quirijn Vos, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, DHHS/NIH/NIAID, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892, (301) 451-2666, qv@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 14, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-32708 Filed 12-20-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIDCR Special Grants Review Committee.

Date: February 23-24, 2012.

Time: 8 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005.

Contact Person: Rebecca Wagenaar Miller, Ph.D., Scientific Review Officer, 6701 Democracy Blvd., Rm 666, Bethesda, MD 20892, (301) 594-0652, rwagenaar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: December 14, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-32675 Filed 12-20-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose