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 anorectally 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.


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.

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 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 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: 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: Qurijn 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, qvos@naiid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases 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.

Billings Code 4140–01–P