

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* October 21, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for XELJANZ (NDA 203214) was submitted on October 21, 2011.

3. *The date the application was approved:* November 6, 2012. FDA has verified the applicant's claim that NDA 203214 was approved on November 6, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by August 11, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 9, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14433 Filed 6–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0928]

Recommendations for Preparation and Submission of Animal Food Additive Petitions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (GFI) #221 entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions.” This guidance describes the types of information that FDA’s Center for Veterinary Medicine recommends for inclusion in food additive petitions submitted for food additives intended for use in food for animals. It is intended to help the petitioner submit this information in a consistent and appropriate manner.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Center for Veterinary Medicine, Division of Animal Feeds (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7077; AskCVM@fda.hhs.gov, in the subject line please include ATTN: Division of Animal Feeds.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 11, 2013 (78 FR 55727), FDA published the notice of availability for a draft guidance entitled “Recommendations for Preparation and Submission of Animal Food Additive Petitions” giving

interested persons until November 12, 2013, to comment on the draft guidance. In the **Federal Register** of December 10, 2013 (78 FR 74154), FDA published a notice reopening the comment period for the draft guidance giving interested persons until January 9, 2014, to comment on the draft guidance.

FDA received four comments on the draft guidance and considered those comments as we finalized the guidance. The guidance announced in this notice finalizes the draft guidance dated September 2013.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on recommendations for preparation and submission of animal food additive petitions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 571.1 and 571.6 have been approved under OMB control number 0910–0546.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: June 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-14364 Filed 6-11-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, July 09, 2015, 09:00 a.m. to July 10, 2015, 01:00 p.m., The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037 which was published in the **Federal Register** on May 13, 2015, 80 FRN27332.

The meeting notice is amended to change the location of the meeting from The Fairmont Washington DC to the Hyatt Regency Bethesda. The date and time remain the same. The meeting is closed to the public.

Dated: June 9, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-14427 Filed 6-11-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, June 25, 2015, 11:00 a.m. to June 25, 2015, 12:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on May 28, 2015, 80 FR 30475.

The meeting will be held on June 24, 2015. The meeting time and location remain the same. The meeting is closed to the public.

Dated: June 9, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-14428 Filed 6-11-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 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 Scientific Review Special Emphasis Panel, PAR Panel: Development of Appropriate Pediatric Formulations and Pediatric Drug Delivery System.

Date: July 8, 2015.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert C Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, 301-435-3009, elliott@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Glia Development, Function and Disease.

Date: July 9, 2015.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213-9887, hamelinc@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowship: Cell Biology, Developmental Biology and Bioengineering.

Date: July 14-15, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander Gubin, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4196, MSC 7812, Bethesda, MD 20892, 301-435-2902, gubina@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Oral, Dental, and Craniofacial Sciences SBIR/STTR.

Date: July 14-15, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Lung Diseases Member Conflicts.

Date: July 14-15, 2015.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: George M Barnas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4220, MSC 7818, Bethesda, MD 20892, 301-435-0696, barnasg@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Nephrology.

Date: July 14-15, 2015.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Atul Sahai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892, 301-435-1198, sahaia@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Neurogenesis and Neurodevelopment.

Date: July 14, 2015.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Laurent Taupenot, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7850, Bethesda, MD 20892, 301-435-1203, laurent.taupenot@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Center on Membrane Protein Production and Analysis (COMPPAA).

Date: July 14-16, 2015.

Time: 5:00 p.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.