

benz[j]aceanthrylene, benzo[a]anthracene, benzo[b]fluoranthene, benzo[k]fluoranthene, benzo[c]phenanthrene, cyclopenta[cd]pyrene, dibenz[a,h]anthracene, dibenzo[a,e]pyrene, dibenzo[a,h]pyrene, dibenzo[a,i]pyrene, dibenzo[a,l]pyrene, indeno[1,2,3-cd]pyrene, and 5-methylchrysene:

15. The different extraction steps used when analyzing PAHs in tobacco filler, smokeless tobacco, and cigarette smoke particulate and any applicable cleanup techniques used.

16. The optimal solvents, extraction solutions, standards, and reference tobacco product(s) needed during the extraction of PAHs from tobacco filler or, as applicable, a Cambridge filter pad.

17. The rationale for using isotopically labeled internal standards instead of targeted surrogates or external standards for PAHs. The number of isotopically labeled internal standards needed to calculate the amount of PAHs in a sample.

18. The challenges with isotopically labeled internal standards, including: (a) The commercial availability of internal standards or their analogs; (b) individual vs. mixture of internal standards, cost of internal standards; (c) deuterated vs. ¹³C labeled internal standards; and (d) concerns of proton exchange with deuterated labeled internal standards.

19. The typical concentration ranges for each of the PAHs listed in this document and any potential method adjustments to accommodate for different cigarette strengths and physical parameters.

20. The major sources of method variability, e.g., include sources from the smoking machine or regimen, sample preparation, separation, and detection of different tobacco product types and strengths.

21. The different methods necessary to separate and detect for PAHs. Provide the number of methods and steps typically used for each from extraction to detection.

22. The specific method challenges and limitations when analyzing testing PAHs, including: (a) Isomer separation and identification, (b) effects of tobacco blend, and (c) low vs. high molecular weight PAHs (volatility and sensitivity).

23. The differences in separation, detection, and limits of detection/quantitation when comparing gas chromatography/mass spectrometry, liquid chromatography/ultraviolet detection, and liquid chromatography/mass spectrometry for PAH analysis.

D. General Method Testing for TNCO, TSNA's, and PAHs in Tobacco Filler (Cigarette, RYO, Smokeless) and Cigarette Smoke

24. The solution stability for prepared solutions and procedures to ensure their integrity.

25. The typical storage conditions and shelf life (i.e., expiration dates) for tobacco product standards and samples.

26. The standard, reference, or known sample solutions used as blanks or for quality control (QC), working, and check standards when testing TNCO, TSNA's, and PAHs.

27. The system suitability and acceptance criteria for each test method. The discussion may include calibration, QC, working, bracketing, and verification standards, confirmation ion ratio for mass spectrometry, chromatographic parameters (i.e., retention times, tailing factor, or peak resolution), injector precision, and blanks.

28. The critical system suitability parameters that are critical when testing TNCO, TSNA's, and PAHs.

29. The actions taken when any system suitability criterion fails, including standards, QC, and subsequent sample analyses.

30. The typical run sequence when testing samples for TNCO, TSNA's, and PAHs.

31. The equations to calculate sample concentrations for TNCO, TSNA's, and PAHs.

32. Examples of chromatograms of reference standards and for measured TNCO, TSNA's, and PAHs in tobacco products.

E. Validation or Method Performance for TNCO, TSNA's, and PAHs in Tobacco Filler (Cigarette, RYO, Smokeless) and Cigarette Smoke

33. The specific details when evaluating each validation parameter, which may include limit of detection, limit of quantification, method detection limit, accuracy, recovery, linearity, range, precision (repeatability), and specificity.

34. The determination of each criterion for each validation parameter when evaluating TNCO, TSNA's, and PAHs.

35. The steps taken when validation parameter criteria are not met.

36. The validation parameters that are performed with reference tobacco products or standards.

37. The types and strengths of tobacco product samples used during validation and method development.

38. The process taken to revalidate a test method when changes to the

method (i.e., solvent, extraction method, or column) are made.

39. The validation process when using a rotary and linear smoking machine with a non-intense and intense smoking regimen.

40. The robustness or ruggedness tests that are conducted for extraction efficiency, solution stability, and small changes in instrument parameters.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: May 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-13084 Filed 6-3-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0559]

Eli Lilly and Co.; Withdrawal of Approval of a New Drug Application for ORAFLEX

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for ORAFLEX (benoxaprofen) Tablets, held by Eli Lilly and Co. (Lilly), Lilly Corporate Center, Indianapolis, IN 46285. Lilly has voluntarily requested that approval of this application be withdrawn, and has waived its opportunity for a hearing.

DATES: Effective June 4, 2013.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6250, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: On April 19, 1982, FDA approved ORAFLEX (benoxaprofen) Tablets, a nonsteroidal

anti-inflammatory drug indicated for the treatment of arthritis. On August 4, 1982, Lilly voluntarily withdrew ORAFLEX (benoxaprofen) Tablets from the market because of postmarketing reports of severe liver toxicity in patients who took ORAFLEX. In a letter dated February 6, 2013, Lilly requested that FDA withdraw approval of NDA 18-250 for ORAFLEX (benoxaprofen) Tablets under § 314.150(d) (21 CFR 314.150(d)). In that letter, Lilly waived any opportunity for a hearing otherwise provided under § 314.150(a). In FDA's letter of February 15, 2013, the Agency acknowledged Lilly's agreement to permit FDA to withdraw approval of ORAFLEX (benoxaprofen) Tablets under § 314.150(d) and waive its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 18-250, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: May 28, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013-13053 Filed 6-3-13; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Children's Study Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Registration is required since space is limited and will begin at 8:00 a.m. Please visit the conference Web site for information on meeting logistics and to register for the meeting at meeting <http://www.cvent.com/d/3cq6zz>. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Children's Study Advisory Committee.

Date: July 23, 2013.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: The Committee will receive an update on the current status of Vanguard Study and will discuss general data collection methods and retention strategy and methods.

Place: National Institutes of Health, Natcher Conference Center, Room E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Kate Winseck, MSW, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5C01, Bethesda, MD 20892, (703) 902-1339, ncs@circlesolutions.com.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. For additional information about the Federal Advisory Committee meeting, please contact Circle Solutions at ncs@circlesolutions.com.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 29, 2013.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-13123 Filed 6-3-13; 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; Systemic Injury by Environmental Exposure.

Date: June 11, 2013.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Bonnie L Burgess-Beusse, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, 301-435-1783, beusseb@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Stroke, Spinal Cord Injury, and Neuroimmunology.

Date: June 14, 2013.

Time: 2:00 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: Samuel C Edwards, Ph.D., IRG CHIEF, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435-1246, edwardss@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 29, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-13124 Filed 6-3-13; 8:45 am]

BILLING CODE 4140-01-P