

TABLE 1—APPROVED NADAs AND ANADAs FOR WHICH REQUIRED REPORTS HAVE NOT BEEN MADE—Continued

NADA/ANADA No.	Trade name (drug)	Sponsor	Citation in 21 CFR
124–391	Nutra-Mix TYLAN-Sulfa Premixes (tylosin phosphate and sulfamethazine).	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	558.630
127–195	TYLAN 10 (tylosin phosphate)	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	558.625
129–415	Custom Ban Wormer 9.6 BANMINTH (pyrantel tartrate).	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.	558.485
130–092	ALFAVET (alfaprostol)	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy	522.46
141–101	PREEMPT (competitive exclusion culture)	Bioscience Division of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704.	529.469
200–187	Isoflurane, USP	Marsam Pharmaceuticals, Inc., Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.	529.1186

Therefore, notice is given to the holders of the approved applications listed in table 1 of this document and to all other interested persons that the Director of the Center for Veterinary Medicine proposes to issue an order under section 512(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(e)) withdrawing approval of the applications, and all amendments and supplements thereto, on the ground that the applicants have failed to submit the reports required under § 514.80(b)(2).

In accordance with section 512 of the FD&C Act and parts 12 and 514 (21 CFR parts 12 and 514), the applicants are hereby provided an opportunity for a hearing to show why the applications listed in table 1 of this document should not be withdrawn (and the corresponding regulations revoked) and an opportunity to raise, for administrative determination, all issues relating to the legal status of the new animal drug products covered by these applications.

An applicant who decides to seek a hearing shall file the following: (1) A written notice of participation and request for a hearing (see DATES), and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see DATES). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 514.200 and in part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 514.200 and part 12, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions

concerning the legal status of the new animal drug products. FDA will then withdraw approval of the applications and the new animal drug products may not thereafter lawfully be marketed, and FDA may begin appropriate regulatory action to remove the products from the market. Any new animal drug product marketed without an approved NADA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 514.80. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs (the Commissioner) will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure by law, the submissions may be seen in the Division of Dockets Management (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday, or on the Internet at <http://www.regulations.gov>.

This notice is issued under section 512 of the FD&C Act and under authority delegated to the Director, Center for Veterinary Medicine, by the Commissioner.

Dated: December 10, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–30089 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. 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.

A portion of 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: Council of Councils.
Open: January 22, 2013, 8:30 a.m. to 12:45 p.m.

Agenda: Program Reports and Presentations; Concept Clearance and Business of the Council.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: January 22, 2013, 12:45 p.m. to 2:00 p.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: January 22, 2013, 2:00 p.m. to 5:00 p.m.

Agenda: Update on Working Group on the Use of Chimpanzees in NIH-Supported Research and Update on National Center for Advancing Translational Sciences.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Robin I. Kawazoe, Executive Secretary, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, Building 1, Room 260, Bethesda, MD 20892, kawazoer@mail.nih.gov.

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. Information is also available on the Council of Council's home page at <http://dpcpsi.nih.gov/council/> where an agenda and proposals to be discussed will be posted before the meeting date.

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. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 10, 2012.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-30333 Filed 12-14-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Cures Acceleration Network Review Board.

The meeting will be open to the public, with attendance limited to space available. 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: Cures Acceleration Network Review Board.

Date: January 23, 2013.

Time: 8:30 a.m. to 2:45 p.m.

Agenda: Report of the Institute Director.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Danilo A Tagle, Ph.D., Associate Director for Special Programs, National Center for Advancing Translational Sciences, 1 Democracy Plaza, Room 992, Bethesda, MD 20892, 301-594-8064, Danilo.Tagle@nih.gov.

Dated: December 11, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-30329 Filed 12-14-12; 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 Meetings

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

The meetings will be open to the public, with attendance limited to space available. 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: AIDS Research Advisory Committee, NIAID.

Date: February 4, 2013.

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

Agenda: Reports from the Division Director and other staff.

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

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892-7601, 301-435-3732.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: June 3, 2013.

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

Agenda: Reports from the Division Director and other staff.

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

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory

Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892-7601, 301-435-3732.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: September 16, 2013.

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

Agenda: Reports from the Division Director and other staff.

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

Contact Person: Rona L. Siskind, Executive Secretary, AIDS Research Advisory Committee, Division of AIDS, NIAID/NIH, 6700B Rockledge Drive, Room 4139, Bethesda, MD 20892-7601, 301-435-3732.

(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 10, 2012.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2012-30330 Filed 12-14-12; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. 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.

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: National Advisory Dental and Craniofacial Research Council.

Date: January 29, 2013.