The guidance represents the Agency's current thinking on food facility registration. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations and section 415 of the FD&C Act. 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 §§ 1.230 through 1.235 and section 415 of the FD&C Act have been approved under OMB control number 0910–0502.

III. Comments

Interested persons may submit either written comments regarding this document to the Division of Dockets Management (see **ADDRESSES**) or electronic comments to *http://www.regulations.gov.* 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Always access an FDA document using the FDA Web site listed previously to find the most current version of the guidance.

Dated: December 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30328 Filed 12–14–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1167]

Ag-Mark, Incorporated, et al.; Proposal To Withdraw Approval of New Animal Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity to request a hearing on the Agency's proposal to withdraw approval of 19 new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required periodic reports for these applications.

DATES: Submit written requests for a hearing by January 16, 2013; submit data and information in support of the hearing request by February 15, 2013.

ADDRESSES: Requests for a hearing, supporting data, and other comments are to be identified with Docket No. FDA–2012–N–1167 and submitted to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9238, email: *vernon.toelle@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new animal drugs are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 514.80 (21 CFR 514.80). The holders of the approved applications listed in table 1 of this document have failed to submit the required annual reports and have not responded to the Agency's repeated requests for submission of the reports including, in all cases, a request by certified mail.

TABLE 1—APPROVED NADAS AND ANADAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN MADE

NADA/ANADA No.	Trade name (drug)	Sponsor	Citation in 21 CFR
009–252	FUMIDIL B (bicyclohexylammonium fumagillin)	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.	520.182
034–601	SYNCHRO–MATE (flurogestone acetate)	G. D. Searle LLC, 4901 Searle Pkwy., Skokie, IL 60077.	529.1003
039–284	Swisher Super Broiler 300–108 (amprolium, ethopabate, bacitracin zinc, and roxarsone).	Swisher Feed Division, William Davies Co., Inc., P.O. Box 578, Danville, IL 61832.	558.58
040–920	Chick Grower-Developer Fortified (amprolium)	Honeggers and Co., Inc., 201 W. Locust St., Fairbury, IL 61739.	Not codified
094–223	Canine Worm Caps (n-butyl chloride)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.	520.260
098–429	Medic-Meal-T Premix (tylosin phosphate)	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.	558.625
098–639	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333–2435.	558.630
106–507	TYLAN 10 (tylosin phosphate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.	558.625
110–044	PRO–TONE Plus Pak GF T–1 (tylosin phosphate)	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.	558.625
117–688	Dichlorophene & Toluene Capsules	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.	520.580
120–614	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363	558.630
120–671	Pet-Worm-Caps (dichlorophene and toluene)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.	520.580
121–147	Nutra-Mix TYLAN (tylosin phosphate)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	558.625
122–522	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.	558.630

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.