DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1167]

Ag-Mark, Inc., et al.; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 19 new animal drug applications (NADAs) and 1 abbreviated new animal drug application (ANADA) from multiple holders of these applications. The basis for the withdrawals is that the holders of these applications have repeatedly failed to file required annual reports for the applications.

DATES: Withdrawal of approval is effective March 18, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6843, *david.alterman@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).

In the **Federal Register** of December, 17, 2012 (77 FR 74672), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 19 NADAs and 1 ANADA because the sponsors had failed to submit the required annual reports for these applications. The holders of these applications did not respond to the NOOH. Failure to file a written notice of participation and request for a hearing as required by § 514.200(b) (21 CFR 514.200(b)) constitutes an election by the applicant not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and a waiver of any contentions concerning the legal status of the drug products. Therefore, the Director, Center for Veterinary Medicine, is withdrawing approval of the 20 applications listed in Table 1 of this document.

TABLE 1—NADAS AND ANADA FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Trade Name (drug)	Applicant
NADA 009–252	FUMIDIL B (bicyclohexylammonium fumagillin)	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214.
NADA 034–601	SYNCHRO–MATE (flurogestone acetate)	G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077.
NADA 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.
NADA 040–920	Chick Grower-Developer Fortified (amprolium)	Honeggers and Co., Inc., 201 W. Locust St., Fairbury, IL 61739.
NADA 094–223	Canine Worm Caps (*n*-butyl chloride)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
NADA 098–429	Medic-Meal-T Premix (tylosin phosphate)	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704.
NADA 098–639	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333–2435.
NADA 106–507	TYLAN 10 (tylosin phosphate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
NADA 110–044	PRO–TONE Plus Pak GF T–1 (tylosin phosphate)	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402.
NADA 117–688	Dichlorophene and Toluene Capsules	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218.
NADA 120–614	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363.
NADA 120–671	Pet-Worm-Caps (dichlorophene and toluene)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214.
NADA 121–147	Nutra-Mix TYLAN (tylosin phosphate)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
NADA 122–522	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
NADA 124–391	Nutra-Mix TYLAN-Sulfa Premixes (tylosin phosphate and sulfamethazine).	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464.
NADA 127–195	TYLAN 10 (tylosin phosphate)	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137.
NADA 129–415	Custom Ban Wormer 9.6 BANMINTH (pyrantel tartrate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501.
NADA 130–092	ALFAVET (alfaprostol)	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy.
NADA 141–101	PREEMPT (competitive exclusion culture)	Bioscience Division, of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704.
ANADA 200–187	Isoflurane, USP	Marsam Pharmaceuticals, LLC, Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034.

The Director, Center for Veterinary Medicine, under section 512(e)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e)(2)(A)), and under authority delegated by the Commissioner, finds that the holders of the applications listed in this document have repeatedly failed to submit reports required by § 514.80. In addition, under § 514.200(b), we find that the holders of the applications have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the applications listed in this document, and all amendments and supplements thereto, is hereby withdrawn, effective March 18, 2013.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these applications.

Dated: February 27, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–04998 Filed 3–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Rural Health Information Technology Network Development Performance Improvement and Measurement System Database (OMB No. 0915–0354)—[Revision]

The purpose of the Rural Health Information Technology Network Development (RHITND) Program, authorized under the Public Health Service Act, Section 330A(f) (42 U.S.C. 254c(f)) as amended by Section 201, Public Law 107–251 of the Health Care Safety Net Amendments of 2002, is to improve health care and support the adoption of Health Information Technology (HIT) in rural America by providing targeted HIT support to rural health networks. HIT plays a significant role in the advancement of Health and Human Services' (HHS) priority policies to improve health care delivery. Some of these priorities include: improving health care quality, safety, and efficiency; reducing disparities; engaging patients and families in managing their health; enhancing care coordination; improving population and public health; and ensuring adequate privacy and security of health information.

The intent of RHITND is to support the adoption and use of electronic health records (EHR) in coordination with the ongoing HHS activities related to the Health Information Technology for Economic and Clinical Health (HITECH) Act (Pub. L. 111–5). This legislation provides HHS with the authority to establish programs to improve health care quality, safety, and efficiency through the promotion of health information technology, including EHR.

For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Office of Rural Health Policy, including: (a) Access to care; (b) the underinsured and uninsured; (c) workforce recruitment and retention; (d) sustainability; (e) health information technology; (f) network development; and (g) health related clinical measures. Several measures will be used for this program. These measures will speak to the Office of Rural Health Policy's progress toward meeting the goals set.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Performance Improvement and Measurement System (PIMS) Database	41	1	41	6.33	259.53
Total	41	1	41	6.33	259.53

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.