

Dated: December 8, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-24102 Filed 12-15-05; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0150]

**Animal Drugs, Feeds, and Related Products; 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 15 new animal drug applications (NADAs) because the products are no longer manufactured or marketed. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to remove portions reflecting approval of the NADAs.

**DATES:** Withdrawal of approval is effective December 27, 2005.

**FOR FURTHER INFORMATION CONTACT:**

Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7519 Standish

Pl., Rockville, MD 20855, 240-276-9067, e-mail: [pesposit@cvm.fda.gov](mailto:pesposit@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** The following sponsors have requested that FDA withdraw approval of the 15 NADAs listed in table 1 of this document because the products are no longer manufactured or marketed:

TABLE 1.

Sponsor	NADA Number, Product (Drug)	21 CFR Section Affected (Sponsor Drug Labeler Code)
Bioproducts, Inc., 320 Springside Dr., Suite 300, Fairlawn, OH 44333-2435	NADA 119-063, Pyrantel Tartrate Ton Pack (pyrantel tartrate)	558.485 (051359)
Farmland Industries, Inc., Kansas City, MO 64116	NADA 138-656, BN Wormer-19.2 BANMINTH Premix (pyrantel tartrate)	558.485 (021676)
I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	NADA 129-395, HYGROMIX 0.6 Premix (hygromycin B) NADA 129-646, TYLAN 10 Sulfa-G (tylosin, sulfamethazine) NADA 136-601, Swine Guard-BN (pyrantel tartrate)	558.274 (050639) 558.630 (050639) 558.485 (050639)
J. & R. Specialty Supply Co., 310 Second Ave., SW,, P.O. Box 506, Waseca, MN 56093	NADA 96-780, TYLAN 10; TYLAN 40 (tylosin)	n/a (049768)
Kerber Milling Co., Box 152, 1817 E. Main St., Emmetsburg, IA 50536	NADA 98-687, Hy-Test Hy-Boost TY 5 Medicated (tylosin)	558.625 (029341)
M & M Livestock Products Co., Eagle Grove, IA 50533	NADA 96-837, M & M Tylosin Premix (tylosin)	558.625 (026282)
Nutra-Blend Corp., P.O. Box 485, Neosho, MO 64850	NADA 129-161, Nutra-Blend TYLAN 10 Sulfa Premix (tylosin, sulfamethazine) NADA 136-384, Swine Wormer-BN BANMINTH (pyrantel tartrate)	558.630 (050568) 558.485 (050568)
South St. Paul Feeds, Inc., 500 Farwell Ave., South St. Paul, MN 55075	NADA 136-369, Custom Ban Wormer 9.6 (pyrantel tartrate)	558.485 (001800)
Stockton Hay & Grain Co.	NADA 49-462, Rainbrook Broiler Premix No. 1 (ampolium, arsanilic acid, ethopabate, penicillin G procaine, streptomycin) NADA 91-646, Rainbow Broiler Base Concentrate (ampolium, bacitracin zinc, ethopabate) NADA 91-647, Broiler Base Concentrate (ampolium, chlortetracycline, ethopabate)	n/a (036541) n/a (036541) n/a (036541)
Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322	NADA 131-146, FLAVOMYCIN 0.4 (bambermycins)	558.95 (011490)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84),

and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 49-462, 91-646,

91-647, 96-780, 96-837, 98-687, 119-063, 129-161, 129-395, 129-646, 131-146, 136-369, 136-384, 136-601, 138-656, and all supplements and

amendments thereto, is hereby withdrawn, effective December 27, 2005.

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 NADAs.

Dated: December 7, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-24103 Filed 12-15-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Joint Meeting of the Nonprescription Drugs Advisory Committee and the Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

##### *Name of Committees:*

Nonprescription Drugs Advisory Committee (NDAC) and the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC).

##### *General Function of the Committees:*

To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on January 23, 2006, from 8 a.m. to 5 p.m.

*Location:* Holiday Inn Select Bethesda, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD. The hotel telephone number is 301-652-2000.

*Contact Person:* Darrell Lyons, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: [lyonsd@cder.fda.gov](mailto:lyonsd@cder.fda.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) codes 3014512541 or 3014512536. Please call the Information Line for up-to-date information on this meeting.

*Agenda:* The committees will consider the safety and efficacy of new drug application (NDA) 21-887, proposing over-the-counter (OTC) use of

ORLISTAT (tetrahydrolipstatin) capsules (60 milligrams (mg)), GlaxoSmithKline Consumer Healthcare, L.P., to promote weight loss in overweight adults when used along with a reduced calorie and low fat diet. The background material will become available no later than the day before the meeting and will be posted under NDAC or EMDAC's docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> (click on the year 2006 and scroll down to NDAC or EMDAC).

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person by January 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 13, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Darrell Lyons at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 2, 2005.

**Jason Brodsky,**

*Acting Associate Commissioner for External Relations.*

[FR Doc. 05-24101 Filed 12-15-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[FDA 225-05-8000]

#### Memorandum of Understanding Between the United States Food and Drug Administration and the C-Path Institute

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the United States Food and Drug Administration and the C-Path Institute. The specific purpose of this MOU is to establish an overarching framework for collaboration between the parties. This framework will be based on mutually agreed upon programs and activities in the areas of applied scientific research and training/education to foster the development of new evaluation tools to inform medical product development. The parties shall each leverage its own expertise and resources to facilitate programs of shared interests across the diverse disciplines of therapeutics, biological sciences, engineering and medical devices in building applied research and training/education programs. The appropriate formal agreements will be executed as required by law for any activities that result from this collaboration.

**DATES:** The agreement became effective October 14, 2005.

**FOR FURTHER INFORMATION CONTACT:** *For C-Path Institute:* Raymond L. Woosley, The Critical Path Institute, 4280 N. Campbell Ave., #214, Tucson, AZ 85718, 520-547-3440, FAX: 520-547-3456, e-mail: [rwoosley@c-path.org](mailto:rwoosley@c-path.org).  
*For The Food and Drug*

*Administration:* Mary I. Poos, Office of External Relations, Food and Drug Administration (HF-10), 5600 Fishers Lane, Rockville, MD 20857, 301-827-2825, FAX: 301-827-3042, e-mail: [mary.poos@fda.gov](mailto:mary.poos@fda.gov).

**SUPPLEMENTARY INFORMATION:** In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 7, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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