

Application No.	Drug	Applicant
ANDA 84-935	DEXEDRINE (dextroamphetamine sulfate) Tablet, 5 mg	GlaxoSmithKline, 5 Moore Dr., P.O. Box 13398, Research Triangle Park, NC 27709-3398.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines the labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-4594 Filed 3-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0002]

Oncologic 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 Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 12, 2011, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, e-mail: caleb.briggs@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 12, 2011, during the morning session, the committee will discuss supplemental new drug application (sNDA) 022334/S-009, trade name AFINITOR (everolimus) tablets, application submitted by Novartis Pharmaceuticals Corp. The proposed indication (use) for this product is for the treatment of patients with advanced neuroendocrine tumors (NET) of gastrointestinal, lung, or pancreatic origin.

During the afternoon session, the committee will discuss sNDA 021938/S-013, trade name SUTENT (sunitinib malate) capsules, application submitted by C.P. Pharmaceuticals International C.V., represented by Pfizer, Inc. (authorized U.S. agent). The proposed indication (use) for this product is for the treatment of unresectable pancreatic neuroendocrine tumors (PNET).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 29, 2011. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person 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 on or before March 21, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 22, 2011.

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 Caleb Briggs at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/>

About Advisory Committees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

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

Dated: February 24, 2011.

Thinh Nguyen,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011-4614 Filed 3-1-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0033]

Withdrawal of Approval of New Animal Drug Applications; Phenylbutazone; Pyrantel; Tylosin; Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of eight new animal drug applications (NADAs). In a final rule

published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations to remove portions reflecting approval of these NADAs.

DATES: Withdrawal of approval is effective March 14, 2011.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, e-mail: *john.bartkowiak@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The sponsors in table 1 have requested that FDA withdraw approval of the three NADAs listed because the products are no longer manufactured or marketed.

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL (WOA) OF THREE NADAS

Sponsor	NADA No. product (established name of drug)	21 CFR Section affected (sponsor drug labeler code)
First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123	NADA 48-647, Phenylbutazone boluses (phenylbutazone)	520.1720a (058829).
Yoder Feed, Division of Yoder, Inc., Kalona, IA 52247	NADA 96-161, Hy-Con TYLAN Premix (tylosin phosphate) ...	558.625 (035369).
Triple "F", Inc., 10104 Douglas Ave., Des Moines, IA 50322 ...	NADA 119-062, Cadco-BN-10 BANMINTH Premix (pyrantel tartrate).	558.485 (011490).

Truow Nutrition, Inc., 1590 Todd Farm Dr., Elgin, IL 60123 (Truow), has informed FDA that it is the sponsor of five feed premix NADAs previously owned by milling companies, which it purchased. NADA 100-352 was owned by NutriBasics Co., last doing business

at P.O. Box 1014, Willmar, MN 56201. NADA 107-002 and NADA 123-000 were owned by Seeco, Inc., also last doing business at P.O. Box 1014, Willmar, MN 56201. NADA 133-833 and NADA 135-243 were owned by Southern Micro-Blenders, Inc., last

doing business at 3801 North Hawthorne St., Chattanooga, TN 37406. Truow has requested that FDA withdraw approval of the five NADAs in table 2 because they are no longer manufactured or marketed.

TABLE 2—VOLUNTARY REQUESTS FOR WOA OF FIVE NADAS BY TRUOW NUTRITION, INC.

Previous sponsor	NADA No., product (established name of drug)	21 CFR section affected (sponsor drug labeler code)
NutriBasics Co., North Highway 71, P.O. Box 1014, Willmar, MN 56201.	NADA 100-352, Seeco T-10 Premix (tylosin phosphate)	558.625 (053740).
Seeco, Inc., P.O. Box 1014, North Highway 71, Willmar, MN 56201.	NADA 107-002, Seeco TYLAN-Sulfa 10 Premix (tylosin phosphate and sulfamethazine).	Not codified.
Seeco, Inc., P.O. Box 1014, North Highway 71, Willmar, MN 56201.	NADA 123-000, Super Swine Wormer B-9 BANMINTH (pyrantel tartrate).	558.485 (011749).
Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406.	NADA 133-833, TYLAN 10 Premix (tylosin phosphate)	558.625 (049685).
Southern Micro-Blenders, Inc., 3801 North Hawthorne St., Chattanooga, TN 37406.	NADA 135-243, Swine Guard-BN BANMINTH Premix (pyrantel tartrate).	558.485 (049685).

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 48-647, 96-161, 100-352, 107-002, 119-062, 123-000, 133-833, and 135-243, and all supplements and

amendments thereto, is hereby withdrawn, effective March 14, 2011.

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: February 18, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-4545 Filed 3-1-11; 8:45 am]

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