

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0262]

Withdrawal of Approval of Part of a New Animal Drug Application; Tiamulin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a tiamulin Type A medicated article that pertain to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. This action is being taken at the sponsor's request because this product is no longer marketed for these uses.

DATES: Withdrawal of approval is effective April 17, 2012.

FOR FURTHER INFORMATION CONTACT:

Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc. (Novartis), 3200 Northline Ave., suite 300, Greensboro, NC 27408, has requested that FDA withdraw approval of those parts of NADA 139-472 for DENAGARD (tiamulin) Type A medicated article pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine. Novartis requested voluntary withdrawal of approval of these indications for use because this product is no longer marketed for these uses. Revised product labeling reflecting the

withdrawal of these indications has been approved in a supplement to NADA 139-472.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of 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 those parts of NADA 139-472 pertaining to the production indications for use of increased rate of weight gain and improved feed efficiency in swine are hereby withdrawn, effective April 17, 2012.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of those parts of NADA 139-472.

Dated: March 21, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-9195 Filed 4-16-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, email

paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1984.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Health Professions Student Loan (HPSL) and Nursing Student Loan (NSL) Programs: Forms (OMB No. 0915-0044)— [Revision]

The HPSL Program provides long-term, low interest loans to students attending schools of medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, and pharmacy. The NSL Program provides long-term, low-interest loans to students who attend eligible schools of nursing in programs leading to a diploma in nursing, an associate degree, a baccalaureate degree, or graduate degree in nursing.

Participating HPSL and NSL schools are responsible for determining the eligibility of applicants, making loans, and collecting monies owed by borrowers on their outstanding loans. The Deferment Form (Deferment-HRSA Form 519) provides the schools with documentation of a borrower's eligibility for deferment. The Annual Operating Report (AOR-HRSA Form 501) relates to HPSL and NSL program operations and financial activities, and provides the Federal Government with information from participating active schools, as well as schools that no longer grant loans, but are required to report and maintain program records, student records, and repayment records until all student loans are repaid in full and all monies due to the Federal Government are returned.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Deferment—HRSA Form 519	3,234	1	3,234	0.533333	1,725
AOR—HRSA—Form 501	834	1	834	12.000000	10,008
Total	4,068	4,068	11,733