(purchases only); other trade-related services; performing arts, sports, and other live performances, presentations, and events; primary insurance premiums (payments only); primary insurance losses recovered; sale or purchase of rights to natural resources, and lease bonus payments; use or lease of rights to natural resources, excluding lease bonus payments; waste treatment and depollution services; and other private services (language translation services; salvage services; security services; account collection services; satellite photography and remote sensing/satellite imagery services; space transport (includes satellite launches, transport of goods and people for scientific experiments, and space passenger transport); and transcription services).

* * * * *

[FR Doc. 05–16305 Filed 8–16–05; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's address for Peptech Animal Health Pty, Ltd.

DATES: This rule is effective August 17, 2005.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.gov*.

SUPPLEMENTARY INFORMATION: Peptech Animal Health Pty, Ltd., 35–41 Waterloo Rd., North Ryde, New South Wales 2113, Australia has informed FDA of a change of address to 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Peptech Animal Health Pty, Ltd.''; and in the table in paragraph (c)(2) by revising the entry for ''064288'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Peptech Animal Health Pty, Ltd., 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia.	064288
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
064288	Peptech Animal Health Pty, Ltd., 19–25 Khartoum Rd., Macquarie Park, New South Wales 2113, Australia
* * * * *	

July 28, 2005.

Bernadette A. Dunham,

Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 05–16280 Filed 8–16–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Phenylbutazone Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Sparhawk Laboratories, Inc. The ANADA provides for the veterinary prescription use of phenylbutazone injectable solution in horses for relief of inflammatory conditions associated with the musculoskeletal system.

DATES: This rule is effective August 17, 2005.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9808, e-mail: *john.harshman@fda.gov*.

SUPPLEMENTARY INFORMATION: Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa , KS 66215–3591, filed ANADA 200–371 for the use of Phenylbutazone 20% Injection by veterinary prescription for relief of inflammatory conditions associated with the musculoskeletal system in horses. Sparhawk Laboratories, Inc.'s, Phenylbutazone 20% Injection is approved as a generic copy of Schering-Plough Animal Health Corp.'s, BUTAZOLIDIN Injectable 20%, approved under NADA 11–575. The ANADA is approved as of July 8, 2005, and the regulations in 21 CFR 522.1720 are amended to reflect the approval. The basis of approval is discussed in the freedom of information(FOI) summary.

In accordance with the FOI provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,