

Related Information

(l) Information related to the subject of this AD can be found in Rolls-Royce Corporation Alert Commercial Engine Bulletins (CEBs), all at Revision 1, and all dated August 30, 2004, listed in the following Table 5:

TABLE 5.—RELATED ALERT
COMMERCIAL ENGINE BULLETINS

CEB-A-313	CEB-A-73-5029
CEB-A-73-2075	CEB-A-73-6041
CEB-A-1394	TP CEB-A-183
CEB-A-73-3118	TP CEB-A-1336
CEB-A-73-4056	TP CEB-A-73-2032

Issued in Burlington, Massachusetts, on July 27, 2006.

Francis A. Favara,

*Manager, Engine and Propeller Directorate,
Aircraft Certification Service.*

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BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

New Animal Drugs; Change of Sponsor; Isoflurane

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 for an abbreviated new animal drug application (ANADA) for isoflurane, U.S.P., from Rhodia UK Ltd. to Nicholas Piramal India Ltd. UK.

DATES: This rule is effective August 3, 2006.

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.hhs.gov.

SUPPLEMENTARY INFORMATION: Rhodia UK Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-237 for isoflurane, U.S.P., to Nicholas Piramal India Ltd. UK, 1st Floor, Alpine House, Unit II, Honeypot Lane, London, NW99RX, England, UK. Accordingly, the regulations are amended in 21 CFR 529.1186 to reflect this change of sponsorship and a current format.

Following these changes of sponsorship, Rhodia UK Ltd. is no longer the sponsor of an approved application. In addition, Nicholas Piramal India Ltd. UK is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Rhodia UK Ltd. to add entries for Nicholas Piramal India Ltd. UK.

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

21 CFR Part 510

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

21 CFR Part 529

Animal drugs.

■ 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 parts 510 and 529 are 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for “Nicholas Piramal India Ltd. UK” and remove the entry for “Rhodia UK Limited”; and in the table in paragraph (c)(2) remove the entry for “059258” and numerically add an entry for “066112” 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
* * *	* * *
Nicholas Piramal India Ltd. UK, 1st Floor, Alpine House, Unit II, Honeypot Lane, London, NW99RX, England, UK.	066112
* * *	* * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * *
066112	Nicholas Piramal India Ltd. UK, 1st Floor, Alpine House, Unit II, Honeypot Lane, London, NW99RX, England, UK
* * *	* * *

PART 529—OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 4. In § 529.1186, in paragraph (b), remove “059258” and numerically add “066112”; and revise paragraph (a), the introductory text of paragraph (c), and paragraph (c)(3) to read as follows:

§ 529.1186 Isoflurane.

(a) *Specifications.* The drug is a clear, colorless, stable liquid.

* * * * *

(c) *Conditions of use.* Administer by inhalation:

* * * * *

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 24, 2006.

Bernadette A. Dunham,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Kanamycin, Bismuth Subcarbonate, Activated Attapulgit

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove inactive ingredients from the specifications for an oral suspension and for tablets containing kanamycin, bismuth subcarbonate, and activated attapulgit; and to consolidate and reformat these sections. These actions are being taken to improve the accuracy