or 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV)). The Division of Drug Information Resources no longer exists. The agency contact for this information is now the Orange Book Staff, Office of Generic Drugs.

In § 314.53(f), FDA is updating the agency unit to which notifications of requests for correction of patent information should be directed. The Drug Information Services Branch no longer exists. These notifications should now be sent to the Office of Generic Drugs Document Room, attention the Orange Book Staff.

In § 314.107(e), FDA is updating the listing of agency units to which a 505(b)(2) applicant must send notification of entry of an order or judgment in a court action. Instead of the appropriate division in the Office of Drug Evaluation I and Office of Drug Evaluation II, these notifications should now be sent to the appropriate division in the Office of New Drugs.

In § 314.107(f)(2)(iv), FDA is updating the agency recipient of a 505(b)(2) applicant's required notification that a legal action has been filed within 45 days of receipt of a notice of paragraph IV certification (submitted under section 505(b)(2)(A)(iv) of the act) from the appropriate division in the Center for Drug Evaluation and Research to the appropriate division in the Office of New Drugs.

In § 314.125(b)(16), FDA is correcting a cross-reference to the agency's regulations on institutional review boards (21 CFR part 56) by replacing ''part 58'' with ''part 56.''

Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because the amendments to the regulations provide only technical changes to correct an inaccurate citation and to update agency contacts, and are nonsubstantive.

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.52 [Amended]

■ 2. Section 314.52 is amended in paragraph (a)(2) by removing ''Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Orange Book Staff, Office of Generic Drugs, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.53 [Amended]

■ 3. Section 314.53 is amended in paragraph (f) by removing ''Drug Information Services Branch (HFD–84), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Office of Generic Drugs, OGD Document Room, Attention: Orange Book Staff, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.95 [Amended]

■ 4. Section 314.95 is amended in paragraph (a)(2) by removing ''Division of Drug Information Resources (HFD–80), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place ''Orange Book Staff, Office of Generic Drugs, at the address identified on FDA's Web site (*http://www.fda.gov/cder/ogd*)''.

§ 314.107 [Amended]

■ 5. Section 314.107 is amended in paragraph (e) by removing ''Office of Drug Evaluation I (HFD–100) or Office of Drug Evaluation II (HFD–500), whichever is applicable,'' and by adding in its place ''Office of New Drugs'' and in paragraph (f)(2)(iv) by removing ''Center for Drug Evaluation and Research'' and by adding in its place ''Office of New Drugs''.

§ 314.125 [Amended]

■ 6. Section 314.125 is amended in paragraph (b)(16) by removing ''part 58'' and by adding in its place ''part 56''.

Dated: February 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy.

[FR Doc. E9–4813 Filed 3–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

[Docket No. FDA–2009–N–0665]

New Animal Drugs; Change of Sponsor; Methoxyflurane

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 a new animal drug application (NADA) from Schering-Plough Animal Health, Inc., to Medical Developments International, Ltd.

DATES: This rule is effective March 6, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 14–485 for ANAFANE (methoxyflurane) Volatile Liquid for Inhalation Anesthesia to Medical Developments International, Ltd., P.O. Box 21, Sandown Village, 3171 VIC Australia.

Medical Developments International, Ltd., is not currently listed in the animal drug regulations as a sponsor of an approved application. In addition, FDA has noticed that this new animal drug has not been previously codified in 21 CFR part 529. Accordingly, the regulations are amended in 21 CFR 510.600(c) to add entries for Medical Developments International, Ltd., and in 21 CFR part 529 to add this new animal drug.

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 ''Medical Developments International, Ltd.''; and in the table in paragraph (c)(2) numerically add an entry for ''025245'' 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
* * *	* *
Medical Developments International, Ltd.,P.O. Box 21, Sandown Village, 3171 VIC Australia	025245
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
025245	Medical Developments International, Ltd.,P.O. Box 21, Sandown Village, 3171 VIC Australia
* *	* * *

* * * * *

PART 529—CERTAIN 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. Add § 529.1455 to read as follows:

§ 529.1455 Methoxyflurane.

(a) *Specifications.* Methoxyflurane liquid.

(b) *Sponsor.* See No. 025245 in § 510.600 of this chapter.

(c) *Conditions of use*—(1) *Amount.* The amount of methoxyflurane used depends on the weight of the patient, the depth of anesthesia, and the type of equipment used. Anesthesia may be induced with methoxyflurane alone, or by the intravenous administration of a short-acting general anesthetic or by inhalation of another anesthetic agent.

(2) *Indications for use.* For the induction and maintenance of general anesthesia.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: March 3, 2009.

Steven D. Vaughn,

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

[FR Doc. E9–4758 Filed 3–5–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0026]

Drawbridge Operation Regulation; Park Street Drawbridge, Oakland Inner Harbor, Alameda, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Park Street drawbridge across the Oakland Inner Harbor, mile 5.2, at Alameda, CA. The deviation is necessary to allow seismic retrofitting of the bridge. This deviation allows single leaf operation of the double leaf, bascule style drawbridge, during the deviation period.

DATES: This deviation is effective from 12:01 a.m. on February 1, 2009 until 11:59 p.m. on May 31, 2009.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of the docket USCG–2009–0026 and are available online at *http://www.regulations.gov*. They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Commander (dpw), Eleventh Coast Guard District, Building 50–2, Coast Guard Island, Alameda, CA 94501–5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516. If you have questions on viewing the docket, call Renee Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The County of Alameda requested a temporary change to the operation of the Park Street drawbridge across the Oakland Inner Harbor, mile 5.2, at Alameda, CA. The Park Street drawbridge navigation span provides a horizontal clearance of 241 feet between pier fenders. During single leaf operation, horizontal clearance is reduced to approximately 100 feet. The drawbridge provides a vertical clearance of 15 feet above Mean High Water in the closed-to-navigation position and unlimited vertical clearance in the open-to-navigation position. As required by 33 CFR 117.181, the draw shall open on signal; except that, from 8 a.m. to 9 a.m. and 4:30 p.m. to 6:30 p.m. Monday through Friday except Federal holidays, the draw need not be opened for the passage of vessels. However, the draw shall open during the above closed periods for vessels which must, for reasons of safety, move on a tide or slack water, if at least two hours notice is given. The waterway is navigated by commercial, recreational, emergency and law enforcement vessels.

Between the hours of 7 a.m. and 9 p.m. Monday through Thursday, and between the hours of 7 a.m. and 3:30 p.m. on Friday, the drawspan will be operated, one leaf at a time, while the opposite leaf, counterweight and hinges are seismically retrofitted. The drawbridge will be operated in the normal double leaf operation mode at night and on weekends, when work is not actually being performed on the bridge. The starting and ending dates for the project are from 12:01 a.m. on February 1, 2009 until 11:59 p.m. on May 31, 2009. This temporary deviation has been coordinated with the waterway users. The largest tug and barge combination on the waterway will be able to continue navigating safely through the bridge. Recreational and