The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for two approved new animal drug applications (NADAs) from Alstoe, Ltd., Animal Health, to Sogeval S.A., and a change of sponsor for an NADA from Nexcyon Pharmaceuticals, Inc. to Elanco Animal Health, A Division of Eli Lilly & Co.

**DATES:** This rule is effective July 24, 2013.

**FOR FURTHER INFORMATION CONTACT:**
Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8300, email: steven.vaughn@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**
Alstoe, Ltd., Animal Health, Pera Innovation Park, Nottingham Rd., Melton Mowbray, Leicestershire, England LE13 0PB has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 099–667 for IMPOSIL (iron dextran complex) Injection and NADA 110–399 for GLEPTOSIL (gleptoferron) Injection to Sogeval S.A., 200 Avenue de Mayenne, 53000 Laval, France.

Nexcyon Pharmaceuticals, Inc., 644 W. Washington Ave., Madison, WI 53703 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–337 for RECUVYRA (fentanyl) Transdermal Solution to Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center,
Indianapolis, IN 46285. Accordingly, the Agency is amending the regulations in 21 CFR parts 522 and 524 to reflect the transfers of ownership.

Following these changes of sponsorship, Alstoe, Ltd., Animal Health, and Nexcyon Pharmaceuticals, Inc., are no longer sponsors of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to remove the entries for these firms.

In addition, Sogeval S.A. is now a sponsor of approved NADAs. Accordingly, FDA is amending 21 CFR 510.600 to add entries for this firm.

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 Parts 522 and 524

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, 522, and 524 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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


2. In the table in paragraph (c)(1) of §510.600, remove the entries for “Alstoe, Ltd., Animal Health” and “Nexcyon Pharmaceuticals, Inc.”, and alphabetically add an entry for “Sogeval S.A.”; and in the table in paragraph (c)(2), remove the entries for “050929” and “062408”, and numerically add an entry for “059120” to read as follows:

   §510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.
   * * * * * * * * * *
   (c) * * *
   (1) * * *

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   (2) * * *

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</table>

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:


§522.1182 [Amended]

4. In §522.1182, in paragraphs (b)(3) and (b)(8), remove “062408” and in its place add “059120”.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 524 continues to read as follows:


§524.916 [Amended]

6. In paragraph (b) of §524.916, remove “050929” and in its place add “000986”.

   Dated: July 17, 2013.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. 2013–17754 Filed 7–23–13; 8:45 am]
BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2013–0636]

RIN 1625–AA00

Safety Zone; Metedeconk River; Brick Township, NJ

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the enforcement date of a safety zone for one recurring fireworks display in the Fifth Coast Guard District. This regulation applies to only one recurring fireworks event held in the Metedeconk River in Brick Township, NJ. The fireworks display is normally held on the first Thursday in September, but this year it will be held on July 25th. The safety zone is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of Delaware River near Philadelphia, Pennsylvania, during the event.

DATES: This rule is effective from 6:30 p.m. on July 25, 2013 through September 5, 2013. Within the Coast Guard Sector Delaware Bay-COTP Zone portion of the table in 33 CFR 165.506, an entry 19 for the Metedeconk River, Brick Township, NJ Safety Zone will be added from 6:30 p.m. until 10 p.m. on July 25, 2013, and existing entry 9 will be suspended on September 5, 2013.

ADDRESSES: Documents mentioned in this preamble are part of docket [USCG–2013–0636]. To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Veronica Smith, U.S. Coast Guard Sector Delaware Bay, Chief of Waterways Management Division; telephone (215) 271–4851, email veronica.l.smith@uscg.mil. If you have questions on viewing or submitting material to the docket, call Barbara