would constitute an allowable exception fails to provide a realistic means for entities to balance these economic and reliability considerations. Instead, I would have provided that an entity could submit its plan to shed firm load for a single contingency to its relevant regulatory authority or governing body prior to any actual interruption.[3] The politically accountable regulatory authority or governing body would have then made the determination, based upon economics and in the best interests of its customers, as to whether firm load shedding should be permitted. Those determinations would be subject to oversight and review by NERC, the Regional Entity, and/or the planning authority to ensure that they will not adversely impact the Bulk Power System.[4]

For these reasons, I respectfully dissent in part and concur in part.

John R. Norris,

Commissioner.

[FR Doc. 2012–10944 Filed 5–4–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Change of Sponsor; Change of Sponsor Address; Change of Sponsor Name and Address; Fomepizole

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 name from Bioniche Teoranta to Mylan Institutional, LLC; a change of sponsor for fomepizole injectable solution from Synerx Pharma, LLC, to Mylan Institutional, LLC; and a change of sponsor address for Modern Veterinary Therapeutics, LLC.

DATES: This rule is effective May 7, 2012.

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: Bioniche Teoranta, Inverin, County Galway, Ireland, has informed FDA that it has changed its name and address to Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103. Synerx Pharma, LLC, 100 N. State St., Newton, PA 18940, has informed FDA that it has transferred ownership of, and all rights and interest in, abbreviated new animal drug application (ANADA) 200–472 for Fomepizole for Injection to Mylan Institutional, LLC. Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146, has informed FDA that it has changed its address to 18001 Old Cutler Rd., suite 317, Miami, FL 33157. Accordingly, the Agency is amending the regulations in parts 510 and 522 (21 CFR parts 510 and 522) to reflect these changes.

Following this change of sponsorship, Synerx Pharma, LLC, is no longer the sponsor of an approved application. Accordingly, § 510.600 (21 CFR 510.600) is being amended to remove the 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 Part 522

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 522 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), remove the entries for ''Bioniche Teoranta'' and ''Synerx Pharma, LLC''; revise the entry for ''Modern Veterinary Therapeutics, LLC''; and alphabetically add a new entry for ''Mylan Institutional, LLC''; and in the table in paragraph (c)(2), remove the entry for ''068882'' and revise the entries for ''015914'' and ''063286'' 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
* * * * *	
Modern Veterinary Therapeutics, LLC, 18001 Old Cutler Rd., suite 317, Miami, FL 33157	015914
* * * * *	
Mylan Institutional LLC, 4901 Hiawatha Dr., Rockford, IL 61103 ..	063286
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
015914	Modern Veterinary Therapeutics, LLC, 18001 Old Cutler Rd., suite 317, Miami, FL 33157.
* * * * *	
063286	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
* * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. In § 522.1004, revise paragraph (b) to read as follows:

§ 522.1004 Fomepizole.

* * * * *

(b) *Sponsors.* See Nos. 046129 and 063286 in § 510.600(c) of this chapter.

* * * * *

Dated: April 30, 2012.

Steven D. Vaughn,

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

[FR Doc. 2012–10892 Filed 5–4–12; 8:45 am]

BILLING CODE 4164–01–P

[3] *See e.g.,* Duke Energy Corporation Dec. 22, 2011 Comments, Docket No. RM11–18–000.

[4] NERC may propose an alternative to Commission guidance that is equally efficient and effective at addressing the Commission's reliability concerns. Order No. 693 at P 31.