PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 4. The authority citation for Part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

§§ 240.12a–10T and 240.12h–1 [Amended]

■ 5. In § 240.12a–10T(b), remove the words ''September 25, 2009'' and add, in their place, the words ''November 30, 2010''.

■ 6. In § 240.12h–1(h)T, in the last sentence, remove the words ''September 25, 2009'' and add, in their place, the words ''November 30, 2010''.

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

■ 7. The authority citation for Part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 77sss, 78*ll*(d), 80b–3, 80b–4, and 80b–11.

§ 260.4d–11T [Amended]

■ 8. Section 260.4d–11T is amended by removing the words ''September 25, 2009'' and adding, in their place, the words ''November 30, 2010'' in the last sentence.

September 14, 2009.

By the Commission.

Elizabeth M. Murphy,

Secretary.

[FR Doc. E9–22389 Filed 9–16–09; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2009–N–0665]

New Animal Drugs; 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 the original approval of an abbreviated new animal drug application (ANADA) filed by Synerx Pharma, LLC. The ANADA provides for the veterinary prescription use of fomepizole injectable solution as an antidote for ethylene glycol (antifreeze) poisoning in dogs.

DATES: This rule is effective September 17, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Synerx Pharma, LLC, 100 N. State St., Newtown, PA 18940–2048, filed ANADA 200–472 that provides for veterinary prescription use of Fomepizole for Injection as an antidote for ethylene glycol (antifreeze) poisoning in dogs. Synerx Pharma, LLC's Fomepizole for Injection is approved as a generic copy of Paladin Laboratories' ANTIZOL–VET (fomepizole), approved under NADA 141–075. The ANADA is approved as of 2009, and the regulations are amended in 21 CFR 522.1004 to reflect the approval.

In addition, Synerx Pharma, LLC, 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 add entries for this sponsor.

In accordance with the freedom of information 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.

FDA has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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), alphabetically add an entry for ''Synerx Pharma, LLC''; and in the table in paragraph (c)(2), numerically add an entry for ''068882'' 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
* * *	* *
Synerx Pharma, LLC, 100 N. State St., Newtown, PA 18940–2048	068882
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
068882	Synerx Pharma, LLC, 100 N. State St., Newtown, PA 18940–2048
* *	* * *

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. 068727 and 068882 in § 510.600(c) of this chapter.

* * * * *

Dated: September 14, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–22384 Filed 9–16–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Parts 22 and 51

[Public Notice 6650]

RIN 1400–AC39

Passport Procedures—Amendment to Expedited Passport Processing Regulation

AGENCY: Bureau of Consular Affairs, State Department.

ACTION: Final Rule.

SUMMARY: This rule revises the expedited passport process and changes the definition of expedited passport processing from three business days, beginning when the application arrives at a passport agency or when the request for expedited processing is approved, to the number of business days published on the Department's Web site at *http://www.travel.state.gov.* This change ensures that the Department can continue to offer this service consistent with its regulations while maintaining sufficient flexibility to adapt to fluctuations in passport demand. It also ensures that the public can easily determine the current standards for expedited passport processing.

DATES: September 17, 2009.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Susan M. Bozinko, Bureau of Consular Affairs, Passport Services, Division of Legal Affairs, U.S. Department of State, Washington, DC 20037 or e-mailed at *BozinkoSM@state.gov.*

SUPPLEMENTARY INFORMATION: The Department published an interim final rule, Public Notice 5888, Vol. 72 **Federal Register** No. 158, amending Parts 22 and 51 of Title 22 of the Code of Federal Regulations, along with a request for comments. The interim final rule was implemented to change the definition of expedited passport processing. The Department's reasons for implementing the change were discussed in detail in the interim final rule. This final rule is unchanged from the interim final rule. Further, this final rule makes a conforming amendment to the Schedule of Fees for Consular Services to reflect a change to the regulation affected by this rule.[1]

Analysis of Comments

Eight comments were submitted in response to the request for comments. Two were unsolicited business offers and one was a test e-mail to ascertain the accessibility of the e-mailbox being used. Five were substantive comments, including comments submitted by the American Immigration Lawyers Association (AILA).

Notice to the Public

Three individuals expressed concern that the publication of the expedited passport processing standard on the Department's Web site would not provide sufficient notice of the standard to the public.

The Department indicates on its Web site the date on which any change to the number of business days constituting expedited passport processing becomes effective. Moreover, the number of business days that constitutes expedited passport processing is a matter of policy determined by the Department. Under 5 U.S.C. 553(b), statements of general agency policy are not subject to the requirement of notice and comment rulemaking. Thus, any modifications of the policy regarding what constitutes expedited passport processing, including changes to the number of business days that constitute expedited processing, are not subject to notice and comment rulemaking.

While one commenter felt that the link to processing times was too difficult to locate, it should be noted that the link appears at the top of the home page for passport information and as such, is readily accessible to anyone seeking information on U.S. passports. In fact, the *http://www.travel.state.gov* Web site was designed with ease of use for the public as a primary goal. The Department believes the current Web site design is sufficient to meet the public's needs.

Nature of Service

Two commenters stated that Web site publication of the expedited processing standard raised the possibility that applicants paying the expedite fee would not receive the same service and that they would not be able to quickly obtain a passport in case of emergency.

Applicants who request expedited service and pay the expedited processing fee can expect to receive expedited processing within the context of circumstances affecting passport application processing times. Changes to the expedited processing time published on the Web site are intended to reflect those circumstances. In addition, citizens in emergency situations have always been and continue to be a priority to the Department. Applicants with urgent travel needs may apply for expedited processing either by mail or in person at a passport agency.

Refunds

One commenter suggested that the Department should provide a waiver of the expedited processing fee or a refund for failure to process expedited passport applications within the time published on the Department's Web site. The Department's regulations at 22 CFR 51.53 already provide for a refund of the expedited processing fee in cases where the Department does not provide expedited processing as defined in 22 CFR 51.56. Applicants seeking such a refund of the expedite fee must submit a written refund request to the Department. Such requests may be submitted to the Department by mail at the address provided on the Department's Web site, *http://www.travel.state.gov,* or by e-mail at the address provided on *http://www.travel.state.gov.* A link to the Department's e-mail portal for expedite fee refund requests is included on the Web site.

Procedural Issues

One commenter said the interim final rule was procedurally deficient because it sought to incorporate by reference information from the Department's Web site in the regulation. The commenter objected to the Department's alleged failure to follow the procedure for incorporation by reference. However, the rules applying to incorporation by reference—contained in 1 CFR Part 51, which implements 5 U.S.C. 552 (*see* the paragraph following 5 U.S.C. 552(a)(1)(E))—normally apply when a rule imposes a burden or regulatory standard on the public. This rule does not regulate the public; rather, it sets the standard for agency conduct. For this reason, the procedures relating to incorporation by reference do not apply to this rule.

[1] A final rule reorganizing and updating the regulations relating to passports, and which incorporated the interim final rule redefining expedited passport processing, was published at 72 FR 64930 (Nov. 19, 2007). As a result of the reorganization implemented by that rule, the regulation affected by this final rule is now at 22 CFR 51.56(b).