

accommodation will impose any new or increased costs on issuers. In the Cost-Benefit Analysis section of the 2004 Adopting Release, we noted that ABS issuers electing the Web-based accommodation provided by Rule 312 would incur costs related to the maintenance and retention of static pool information posted on a Web site and might also incur start-up costs.³⁶ While it is likely that certain of those costs will continue to impact ABS issuers that elect the Web-based approach during the extension period, we do not believe the amendment will impose any new or increased costs for ABS issuers because it does not change any other conditions to the accommodation or the underlying filing and disclosure obligations. As a result of the extension of the accommodation, ABS issuers will be able to continue their current practices for an additional year.

For investors, there may be costs associated with the static pool information not being electronically filed with the Commission. For example, when information is electronically filed with the Commission, investors and staff can access the information from a single, centralized location, the EDGAR Web site. We think these costs are mitigated by the fact that ABS issuers relying on the Rule 312 accommodation must ensure that the prospectus for the offering contains the Internet Web site address where the static pool information is posted, the Web site must be unrestricted and free of charge, such information must remain on the Internet Web site for five years with any changes clearly indicated and the issuer must undertake to provide the information to any person free of charge, upon request, if a subsequent update or change is made. Furthermore, because the information is deemed included in the prospectus under Rule 312, it is subject to all liability provisions applicable to prospectuses and registration statements.

Investors and issuers may have incurred costs to adjust their processes in anticipation of the lapse of the Rule 312 accommodation and potential reversion to a requirement to file static pool information on EDGAR. In this case, benefits to investors or issuers of not having to change their procedures regarding static pool reporting in a short time frame would be diminished by any costs already incurred in anticipation of the change. We believe such anticipatory action and any associated costs are minimal.

IV. Consideration of Impact on the Economy, Burden on Competition, and Promotion of Efficiency, Competition, and Capital Formation

Section 2(b) of the Securities Act requires us, when engaging in rulemaking where we are required to consider or determine whether an action is necessary or appropriate in the public interest, to also consider whether the action will promote efficiency, competition, and capital formation.

As discussed in greater detail above, Rule 312 of Regulation S-T was adopted as a temporary filing accommodation so that issuers of ABS could present static pool information on an Internet Web site. The amendment to Rule 312 of Regulation S-T that we are adopting today extends its application for one year. We are not changing the conditions of Rule 312 or the disclosure obligations to which it applies. We do not believe that the one-year extension will impose a burden on competition. We also believe the extension of the filing accommodation will continue to promote efficiency and capital formation by permitting ABS issuers to disclose static pool information in a format that is more useful to investors and cost-effective and not unduly burdensome for ABS issuers.

We requested comment on whether the proposed amendment, if adopted, would promote efficiency, competition, and capital formation. We did not receive any comments directly responding to this request.

V. Regulatory Flexibility Analysis Certification

In Part VI of the Proposing Release, the Commission certified pursuant to Section 605(b) of the Regulatory Flexibility Act³⁷ that the proposed amendment to Rule 312 of Regulation S-T would not have a significant economic impact on a substantial number of small entities. While the Commission encouraged written comments regarding this certification, no commenters responded to this request or indicated that the amendment as adopted would have a significant economic impact on a substantial number of small entities.

VI. Statutory Authority and Text of the Final Amendment

The amendment described is being adopted under the authority set forth in Sections 6, 7, 10, 19 and 28 of the Securities Act of 1933 (15 U.S.C. 77f, 77g, 77j, 77s, and 77z-3).

List of Subjects

17 CFR Part 232

Reporting and recordkeeping requirements, Securities.

Text of the Amendment

■ For the reasons set out in the preamble, the Commission hereby amends title 17, chapter II, of the Code of Federal Regulations as follows:

PART 232—REGULATION S-T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 1. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 78l, 78m, 78n, 78o(d), 78w(a), 78ll, 80a-6(c), 80a-8, 80a-29, 80a-30, 80a-37, and 7201 *et seq.*; and 18 U.S.C. 1350.

* * * * *

§ 232.312 [Amended]

■ 2. Amend § 232.312 by removing “December 31, 2009” and in its place adding “December 31, 2010” in the first sentence of paragraph (a).

By the Commission.

Dated: December 15, 2009.

Florence E. Harmon,
Deputy Secretary.

[FR Doc. E9-30185 Filed 12-18-09; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA-2009-N-0665]

Implantation or Injectable Dosage Form New Animal Drugs; Polysulfated Glycosaminoglycan

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Luitpold Pharmaceuticals, Inc. The supplemental NADA provides for additional vial sizes for an injectable solution of polysulfated glycosaminoglycan.

DATES: This rule is effective December 21, 2009.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary

³⁶ See 2004 Adopting Release, Section V.D.

³⁷ 5 U.S.C. 605(b).

Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8337, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967, filed a supplement to NADA 140-901 for ADEQUAN (polysulfated glycosaminoglycan), an injectable solution approved for use in horses and dogs by veterinary prescription for noninfectious degenerative and/or traumatic joint disease. The supplemental NADA provides for additional vial sizes. The application is approved as of November 10, 2009, and the regulations are amended in 21 CFR 522.1850 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under § 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 in 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 522.1850, revise paragraph (a) to read as follows:

§ 522.1850 Polysulfated glycosaminoglycan.

(a) *Specifications.* (1) Each 1-milliliter (mL) ampule of solution contains 250 milligrams (mg) polysulfated glycosaminoglycan.

(2) Each mL of solution packaged in 5-mL ampules or 20-, 30-, or 50-mL vials contains 100 mg polysulfated glycosaminoglycan.

* * * * *

Dated: December 15, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9-30222 Filed 12-18-09; 8:45 am]

BILLING CODE 4160-01-S

POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2010-9 and CP2010-9; Order No. 344]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is adding Priority Mail Contract 23 to the Competitive Product List. This action is consistent with changes in a recent law governing postal operations. Republication of the lists of market dominant and competitive products is also consistent with new requirements in the law.

DATES: Effective December 21, 2009 and is applicable beginning October 28, 2009.

FOR FURTHER INFORMATION CONTACT:

Stephen L. Sharfman, General Counsel, 202-789-6820 or stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION: *Regulatory History*, 74 FR 59015 (November 16, 2009).

- I. Introduction
- II. Background
- III. Comments
- IV. Commission Analysis
- V. Ordering Paragraphs

I. Introduction

The Postal Service seeks to add a new product identified as Priority Mail Contract 23 to the Competitive Product List. For the reasons discussed below, the Commission approves the Request.

II. Background

Pursuant to 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 23 to the Competitive Product List.¹ The Postal Service asserts that Priority Mail Contract 23 is a competitive product “not of general applicability” within the meaning of 39 U.S.C. 3632(b)(3). The Postal Service states that prices and classification underlying this contract are supported

¹ Request of the United States Postal Service to Add Priority Mail Contract 23 to Competitive Product List and Notice of Filing (Under Seal) of Contract and Supporting Data, November 5, 2009 (Request).

by Governors’ Decision No. 09-06 in Docket No. MC2009-25. *Id.* at 1. The Request has been assigned Docket No. MC2010-9.

The Postal Service contemporaneously filed a contract related to the proposed new product pursuant to 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. The contract has been assigned Docket No. CP2010-9.

In support of its Request, the Postal Service filed the following materials: (1) A redacted version of the Governors’ Decision, originally filed in Docket No. MC2010-25, authorizing certain Priority Mail contracts;² (2) a redacted version of the contract;³ (3) a requested change in the Competitive Product List;⁴ (4) a Statement of Supporting Justification as required by 39 CFR 3020.32;⁵ (5) a certification of compliance with 39 U.S.C. 3633(a);⁶ and (6) an application for non-public treatment of the materials filed under seal.⁷

In the Statement of Supporting Justification, Mary Prince Anderson, Manager, Sales and Communications, Expedited Shipping, asserts that the service to be provided under the contract will cover its attributable costs, make a positive contribution to institutional costs, and increase contribution toward the requisite 5.5 percent of the Postal Service’s total institutional costs. *Id.*, Attachment D. Thus, Ms. Anderson contends there will be no issue of subsidization of competitive products by market dominant products as a result of this contract. *Id.*

A redacted version of the specific Priority Mail Contract 23 is included with the Request. The contract will become effective on the day that the Commission provides all necessary regulatory approvals. It is terminable upon 30 days’ notice by either party, but could continue for up to one year. The Postal Service represents that the contract is consistent with 39 U.S.C. 3633(a). *See id.*, Attachment D. The Postal Service will provide Priority Mail packaging for items mailed by the shipper.

The Postal Service filed much of the supporting materials, including the specific Priority Mail Contract 23, under seal. In its Request, the Postal Service maintains that the contract and related financial information, including the customer’s name and the accompanying

² Attachment A to the Request, reflecting Governors’ Decision No. 09-06, April 27, 2009.

³ Attachment B to the Request.

⁴ Attachment C to the Request.

⁵ Attachment D to the Request.

⁶ Attachment E to the Request.

⁷ Attachment F to the Request.