and 211(a) of the Advisers Act [15 U.S.C. 80b–6a and 80b–11(a)].

List of Subjects in 17 CFR Part 275

Investment advisers, Reporting and recordkeeping requirements.

Text of Rule Amendment

For the reasons set out in the preamble, Title 17, Chapter II of the Code of Federal Regulations is amended as follows.

PART 275—RULES AND REGULATIONS, INVESTMENT ADVISERS ACT OF 1940

■ 1. The authority citation for Part 275 continues to read in part as follows:

Authority: 15 U.S.C. 80b–2(a)(11)(G), 80b–2(a)(11)(H), 80b–2(a)(17), 80b–3, 80b–4, 80b–4a, 80b–6(4), 80b–6a, and 80b–11, unless otherwise noted.

* * * * *

§ 275.206(3)–3T [Amended]

■ 2. In § 275.206(3)–3T, amend paragraph (d) by removing the words ''December 31, 2014'' and adding in their place ''December 31, 2016.''

By the Commission.

Dated: December 17, 2014.

Brent J. Fields,

Secretary.

[FR Doc. 2014–29975 Filed 12–22–14; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 316

[Docket No. FDA–2011–N–0583]

Policy on Orphan-Drug Exclusivity; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; clarification on policy.

SUMMARY: The Food and Drug Administration (FDA) is publishing this document to clarify its policy regarding certain aspects of orphan-drug exclusivity. This document is being published because of a recent court decision interpreting provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Orphan Drug Act.

DATES: Effective December 23, 2014.

FOR FURTHER INFORMATION CONTACT: Gayatri R. Rao, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5271, Silver Spring, MD 20993, 301–796–8660.

SUPPLEMENTARY INFORMATION:

I. Background

After a designated orphan drug is approved, section 527 of the FD&C Act (21 U.S.C. 360cc) generally prohibits the Food and Drug Administration (FDA or the Agency) from approving another such drug for the same disease for 7 years. Regulations interpreting this provision were proposed in 1991 (January 29, 1991, 56 FR 3338) and made final in 1992 (December 29, 1992, 57 FR 62076). In 2011, FDA issued a proposed rule (October 19, 2011, 76 FR 64868) to amend these regulations to clarify certain regulatory language and propose areas of minor improvement regarding orphan-drug designation and orphan-drug exclusivity; these were finalized in 2013 (June 12, 2013, 78 FR 35117). These regulations are codified under part 316 (21 CFR part 316).

FDA has interpreted section 527 of the FD&C Act and its regulations such that the Agency will not recognize orphan-drug exclusivity for a drug when it has previously approved the same drug for the same use or indication in a rare disease or condition. §§ 316.3(b)(12); 316.31(a). A drug will not be considered the same as a previously approved drug if, at the time of approval, the sponsor has provided evidence that its drug is ''clinically superior'' to the previously approved drug, that is, the drug is more effective, safer, or makes a major contribution to patient care. § 316.3(b)(3). Accordingly, the sponsor of an orphan-designated drug that is the same as a previously approved drug, as defined in § 316.3(b)(14), is required to demonstrate that its drug is clinically superior to the previously approved drug in order for its drug to be eligible for orphan-drug exclusivity upon approval.

The Agency's interpretation of section 527 of the FD&C Act has been the subject of legal action in *Depomed* v. *HHS et al.*, Civil Action No. 12–1592 (KBJ) (D.D.C. September 5, 2014). Depomed has not demonstrated that GRALISE (gabapentin) is clinically superior to a previously approved drug, Pfizer's NEURONTIN (gabapentin). Accordingly, under the relevant regulations, GRALISE is the same drug as NEURONTIN, because it contains the same active moiety (gabapentin), was approved for the same use (post-herpetic neuralgia), and was not demonstrated to be clinically superior to NEURONTIN. Nevertheless, the *Depomed* court held that FDA must recognize orphan-drug exclusivity for GRALISE for the treatment of post-herpetic neuralgia. Following the *Depomed* decision, under the court's order, FDA recognized orphan-drug exclusivity for GRALISE for the treatment of post-herpetic neuralgia.

II. Orphan-Drug Exclusivity

In consideration of any uncertainty created by the court's decision in *Depomed,* the Agency is issuing this statement. It is the Agency's position that, given the limited terms of the court's decision to GRALISE, FDA intends to continue to apply its existing regulations in part 316 to orphan-drug exclusivity matters. FDA interprets section 527 of the FD&C Act and its regulations (both the older regulations that still apply to original requests for designation made on or before August 12, 2013, as well as the current regulations) to require the sponsor of a designated drug that is the ''same'' as a previously approved drug to demonstrate that its drug is ''clinically superior'' to that drug upon approval in order for the subsequently approved drug to be eligible for orphan-drug exclusivity.

Dated: December 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29920 Filed 12–22–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 151

[K00103 14/15 A3A10; 134D0102DR–DS5A300000–DR.5A311.IA000115]

RIN 1076–AF23

Land Acquisitions in the State of Alaska

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Final rule.

SUMMARY: This rule deletes a provision in the Department of the Interior's land-into-trust regulations that excludes from the scope of the regulations, with one exception, land acquisitions in trust in the State of Alaska.

DATES: This rule is effective January 22, 2015.

FOR FURTHER INFORMATION CONTACT: Elizabeth Appel, Director, Office of Regulatory Affairs & Collaborative Action, (202) 273–4680; *elizabeth.appel@bia.gov.*