Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1255.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 27, 2022 (87 FR 58445), we amended the color additive regulations in § 73.70 (21 CFR 73.70) ''Calcium Carbonate'' by expanding the permitted uses of calcium carbonate to include use in dietary supplement tablets and capsules, including coatings and printing inks, in amounts consistent with good manufacturing practice.

We gave interested persons until October 27, 2022, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. We received a comment requesting a revision to the regulation that would account for a possible change to the standard of identity for chocolate. We note, however, that the rule already contains language to allow the use of calcium carbonate if the standard of identity for chocolate changes in the future, and that the rule's text is more precise than that requested by the comment because ''added color'' (21 CFR 73.70(c)) refers back to calcium carbonate only, whereas the comment's suggested change could be interpreted as covering additional color additives. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of September 27, 2022, should be confirmed.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs, we are giving notice that no objections or requests for a hearing were filed in response to the September 27, 2022, final rule. Accordingly, the amendments issued thereby became effective October 28, 2022.

Dated: January 17, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01185 Filed 1–23–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 316

[Docket No. FDA–2011–N–0583]

Clarification of Orphan-Drug Exclusivity Following Catalyst Pharms., Inc. v. Becerra; Notification

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing this notification in light of the recent decision by the U.S. Court of Appeals for the Eleventh Circuit in *Catalyst Pharms., Inc.* v. *Becerra.* The *Catalyst* decision addressed the orphan-drug exclusivity provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Orphan Drug Act and subsequent amendments, and concluded that FDA's approval of Jacobus Pharmaceutical Company's (Jacobus's) drug (the drug at issue in the litigation) must be set aside. Consistent with the court's decision, FDA has set aside its approval of Jacobus's drug. This notification announces that, at this time, while complying with the court's order in *Catalyst,* FDA intends to continue to apply its regulations tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved to matters beyond the scope of that order.

DATES: The policy set out in this document is effective January 24, 2023.

FOR FURTHER INFORMATION CONTACT: Aaron Friedman, Office of Orphan Products Development, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2989.

SUPPLEMENTARY INFORMATION:

I. Background

On September 30, 2021, the U.S. Court of Appeals for the Eleventh Circuit issued a decision in *Catalyst Pharms., Inc.* v. *Becerra* (*Catalyst*), 14 F.4th 1299 (11th Cir. 2021).

At the time of the litigation, Jacobus and Catalyst Pharmaceuticals (Catalyst) each had orphan-drug designation for the drug amifampridine for the treatment of Lambert-Eaton myasthenic syndrome (LEMS). In November 2018, FDA approved Catalyst's drug for the treatment of LEMS in adults. FDA recognized Catalyst's drug as eligible for orphan-drug exclusivity for its only approved indication—the treatment of LEMS in adults.

In May 2019, FDA approved Jacobus's drug for the treatment of LEMS in children. In approving Jacobus's drug, FDA followed its longstanding rule, codified in its regulations, that the orphan-drug exclusivity for Catalyst's drug protected only the approved use or indication within the designated disease. *See* 21 CFR 316.3(b)(12), 316.31(a)–(b). The regulation in 21 CFR 316.31(b) states, in part, that: ''Orphan-drug exclusive approval protects *only the approved indication or use of a designated drug.*'' [1]

In June 2019, Catalyst filed suit against FDA, challenging FDA's approval of Jacobus's application under the Administrative Procedure Act, 5 U.S.C. 701–706. Among other things, Catalyst argued that the phrase ''same disease or condition'' in the Orphan Drug Act, 21 U.S.C. 360cc(a), unambiguously prohibited FDA from approving Jacobus's drug application. Specifically, Catalyst argued that the Orphan Drug Act required orphan-drug exclusivity to extend to *all* uses or indications within the orphan-designated disease or condition—even uses or indications for which Catalyst had not received approval, such as the treatment of LEMS in children.

The district court rejected Catalyst's argument that the Orphan Drug Act required orphan-drug exclusivity to apply to all uses or indications within the orphan-designated disease or condition. The district court concluded that, given the context and the overall statutory scheme, the statute was ambiguous on the disputed issue, and that FDA had reasonably interpreted the statute to tie orphan-drug exclusivity to the uses or indications for which the drug was approved.

On appeal, the U.S. Court of Appeals for the Eleventh Circuit reversed. The circuit court concluded that the phrase ''same disease or condition'' in the Orphan Drug Act, 21 U.S.C. 360cc(a), unambiguously foreclosed FDA's interpretation of the provision. Accordingly, the circuit court held that orphan-drug exclusivity for Catalyst's

[1] Emphasis added. Other regulatory provisions also reflect the understanding that orphan-drug exclusivity is tied to the use or indication for which the drug was approved. *See* § 316.3(b)(12) (stating that ''no approval will be given to a subsequent sponsor of the same drug for the *same use or indication* for 7 years'' (emphasis added)); *see also id.* § 316.31(a) (explaining that FDA may approve an orphan drug for ''select *indication(s) or use(s)* within the rare disease or condition for which the drug was designated'' and that ''FDA will not approve another sponsor's marketing application for the same drug for the *same use or indication* before the expiration of 7 years from the date of such approval'' (emphases added)).

drug blocked FDA's approval of Jacobus's drug for *all* uses or indications within the orphan-designated disease (LEMS)—even though Catalyst's drug was approved at that time only for use in the treatment of LEMS in adults. The court concluded that FDA's approval of Jacobus's drug for the treatment of LEMS in children must be set aside. Consistent with the court's decision, the Agency set aside the approval of Jacobus's drug.

II. Orphan-Drug Exclusivity

The Agency is issuing this statement to address the uncertainty created by the circuit court's decision in *Catalyst.* The court ordered FDA to set aside its approval of Jacobus's drug, and FDA has set aside that approval. This notification announces that, at this time, in matters beyond the scope of that court order, FDA intends to continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. The Agency believes that this approach is appropriate for several reasons. FDA continues to believe that the statutory text does not unambiguously require that orphan-drug exclusivity extend to the entire disease or condition for which a drug received orphan-drug designation if the drug is only approved for some uses within that disease or condition. Further, FDA believes that its statutory interpretation embodied in its regulations best advances the Orphan Drug Act's purposes, appropriately balancing the need to incentivize the development of drugs for rare diseases and conditions with the need to provide patient access to orphan drugs. The regulations accomplish this by tying the scope of orphan-drug exclusivity to only the approved use or indication of the drug, which permits other sponsors to obtain approval of the drug for uses or indications within the same orphan-designated disease or condition that have not yet been approved (*i.e.,* that are ''new''). Under the regulations, a drug approved for a new use or indication within the same orphan-designated disease or condition may also be eligible for orphan-drug exclusivity for such use or indication. These regulations incentivize sponsors to continue to develop a drug for use in all persons affected by a rare disease or condition. Thus, FDA believes that continued adherence to its validly promulgated regulations will best serve the public health by facilitating patient access to orphan drugs, especially for difficult-to-study patients such as young children.

III. Conclusion

For the above reasons, at this time, the Agency intends to continue to apply its longstanding regulations tying the scope of orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

Dated: January 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–01179 Filed 1–23–23; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R2–ES–2021–0015; FF09E21000 FXES1111090FEDR 234]

RIN 1018–BB27

Endangered and Threatened Wildlife and Plants; Lesser Prairie-Chicken; Threatened Status With Section 4(d) Rule for the Northern Distinct Population Segment and Endangered Status for the Southern Distinct Population Segment; Delay of Effective Date

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; delay of effective date.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are delaying the effective date of a final rule we published on November 25, 2022, and corrected on December 2, 2022, listing two distinct population segments (DPSs) of the lesser prairie-chicken (*Tympanuchus pallidicinctus*) under the Endangered Species Act of 1973, as amended (Act) and establishing measures that are necessary and advisable to provide for the conservation of the Northern DPS pursuant to section 4(d) of the Act. This delay is necessary for the Service to finalize conservation tools and guidance documents to avoid confusion and disruption with Federal agencies in the implementation of section 7 of the Act and to avoid disruption to the public who would be regulated by the rule.

DATES: The effective date of the final rule that published on November 25, 2022, at 87 FR 72674, and corrected on December 2, 2022, at 87 FR 73971, is delayed from January 24, 2023, to March 27, 2023.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov.* For access to the docket to read the November 25, 2022, final rule or other background documents, including the comments received on that final rule, go to *https://www.regulations.gov* and search for Docket No. FWS–R2–ES–2021–0015.

FOR FURTHER INFORMATION CONTACT: Beth Forbus, Regional Endangered Species Program Manager, Southwest Regional Office, 500 Gold Ave. SW, Albuquerque, NM 87102; telephone 505–318–8972. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Background

On November 25, 2022, we published in the **Federal Register** (87 FR 72674) a final rule listing two DPSs of the lesser prairie-chicken (*Tympanuchus pallidicinctus*), a grassland bird known from southeastern Colorado, western Kansas, eastern New Mexico, western Oklahoma, and the Texas Panhandle. We determined threatened status for the Northern DPS and endangered status for the Southern DPS. This rule will add the DPSs to the List of Endangered and Threatened Wildlife. We also finalized a rule under the authority of section 4(d) of the Act that provides measures that are necessary and advisable to provide for the conservation of the Northern DPS. The rule was to be effective on January 24, 2023; however, with this final rule, we are delaying the effective date to March 27, 2023. This delay will allow us to finalize conservation tools and guidance documents and prevent confusion and disruption with other Federal agencies under section 7 of the Act.

Currently, the lesser prairie-chicken is not listed under the Act. When the November 25, 2022, final rule goes into effect, the Southern DPS will be classified as endangered. This will initiate the prohibitions set forth in section 9 of the Act and the consultation obligations set forth in section 7 of the Act. Also when the final rule goes into effect, the Northern DPS will be classified as threatened with a section 4(d) rule that tailors the prohibitions and exceptions to the prohibitions necessary and advisable for the species. The consultation obligations set forth in section 7 of the Act will also be applicable to the Northern DPS. We recognize that these changes in status