EDGAR—Information for Filers web page on *www.SEC.gov,* where it can be consulted by interested filers.

Finally, Volume II is amended to reflect minor software updates made to EDGAR after the Commission last approved changes to the Filer Manual.[13] The software changes relate to changes to the technical specifications for submission types 144 and 144/A.

IV. Amendments to Rule 301 of Regulation S–T

Along with the adoption of the updated Filer Manual, we are amending Rule 301 of Regulation S–T to provide for the incorporation by reference into the Code of Federal Regulations of the current revisions. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

The updated EDGAR Filer Manual is available at *https://www.sec.gov/edgar/filer-information/current-edgar-filer-manual.*

V. Administrative Law Matters

Because the Filer Manual and rule amendments relate solely to agency procedures or practice and do not substantially alter the rights and obligations of non-agency parties, publication for notice and comment is not required under the Administrative Procedure Act (''APA'').[14] It follows that the amendments do not require analysis under requirements of the Regulatory Flexibility Act [15] or a report to Congress under the Small Business Regulatory Enforcement Fairness Act of 1996.[16]

The effective date for the updated Filer Manual and related rule amendments is January 24, 2023. In accordance with the APA,[17] we find that there is good cause to establish an effective date less than 30 days after publication of these rules. The Commission believes that establishing an effective date less than 30 days after publication of these rules is necessary to coordinate the effectiveness of the updated Filer Manual with the related system upgrades.

VI. Statutory Basis

We are adopting the amendments to Regulation S–T under the authority in Sections 6, 7, 8, 10, and 19(a) of the Securities Act of 1933,[18] Sections 3, 12, 13, 14, 15, 15B, 23, 35A, and 36 of the Securities Exchange Act of 1934,[19] Section 319 of the Trust Indenture Act of 1939,[20] Sections 8, 30, 31, and 38 of the Investment Company Act of 1940,[21] and Sections 203, 204, 206A, 210, and 211 of the Investment Advisers Act of 1940.[22]

List of Subjects in 17 CFR Part 232

Incorporation by reference, Reporting and recordkeeping requirements, Securities.

Text of the Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

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

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

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z–3, 77sss(a), 78c(b), 78*l,* 78m, 78n, 78o(d), 78w(a), 78*ll,* 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 80b–4, 80b–6a, 80b–10, 80b–11, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 2. Section 232.301 is revised to read as follows:

§ 232.301 EDGAR Filer Manual.

Filers must prepare electronic filings in the manner prescribed by the EDGAR Filer Manual, promulgated by the Commission, which sets forth the technical formatting requirements for electronic submissions. The requirements for becoming an EDGAR Filer and updating company data are set forth in the EDGAR Filer Manual, Volume I: ''General Information,'' Version 41 (December 2022). The requirements for filing on EDGAR are set forth in the updated EDGAR Filer Manual, Volume II: ''EDGAR Filing,'' Version 64 (December 2022). All of these provisions have been incorporated by reference into the Code of Federal Regulations, which action was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You must comply with these requirements in order for documents to be timely received and accepted. The EDGAR Filer Manual is available for inspection at the Commission and at the National Archives and Records Administration (NARA). The EDGAR Filer Manual is available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Operating conditions may limit access to the Commission's Public Reference Room. For information on the availability of the EDGAR Filer Manual at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email *fr.inspection@nara.gov.* The EDGAR Filer Manual may also be obtained from *https://www.sec.gov/edgar/filer-information/current-edgar-filer-manual.*

By the Commission.

Dated: December 19, 2022.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2023–01200 Filed 1–23–23; 8:45 am]

BILLING CODE 8011–01–P

[13] Software changes to EDGAR were made in EDGAR Release 22.3.1, deployed on October 17, 2022.

[14] 5 U.S.C. 553(b)(A).

[15] 5 U.S.C. 601 through 612.

[16] 5 U.S.C. 804(3)(C).

[17] 5 U.S.C. 553(d)(3).

[18] 15 U.S.C. 77f, 77g, 77h, 77j, and 77s(a).

[19] 15 U.S.C. 78c, 78*l,* 78m, 78n, 78*o,* 78o–4, 78w, and 78*ll.*

[20] 15 U.S.C. 77sss.

[21] 15 U.S.C. 80a–8, 80a–29, 80a–30, and 80a–37.

[22] 15 U.S.C. 80b–3, 80b–4, 80b–6a, 80b–10, and 80b–11.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2017–C–6238]

Listing of Color Additives Exempt From Certification; Calcium Carbonate; Confirmation of Effective Date

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

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of October 28, 2022, for the final rule that appeared in the **Federal Register** of September 27, 2022, and that amended the color additive regulations to provide for the safe use of calcium carbonate in dietary supplement tablets and capsules.

DATES: Effective date of final rule published in the **Federal Register** of September 27, 2022 (87 FR 58445) confirmed: October 28, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christopher Kampmeyer, Center for

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)).