



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2017-C-0935]

Listing of Color Additives Subject to Certification; D&C Black No. 4; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of July 10, 2018, for the final rule that appeared in the *Federal Register* of June 7, 2018, and that amended the color additive regulations to provide for the safe use of D&C Black No. 4 for coloring ultra-high molecular weight polyethylene (UHMWPE) non-absorbable sutures for use in general surgery.

DATES: Effective date of final rule published in the *Federal Register* of June 7, 2018 (83 FR 26356) confirmed: July 10, 2018.

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: Joseph M. Thomas, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740-3835, 301-796-9465.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of June 7, 2018 (83 FR 26356), we amended the color additive regulations to add § 74.3054, “D&C Black No. 4,” (21 CFR 74.3054) to provide for the safe use of D&C Black No. 4 for coloring UHMWPE non-absorbable sutures for use in general surgery.

We gave interested persons until July 9, 2018, to file objections or requests for a hearing. We received no objections or requests for a hearing on the final rule. Therefore, we find that the effective date of the final rule that published in the *Federal Register* of June 7, 2018, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

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 June 7, 2018, final rule. Accordingly, the amendments issued in the final rule became effective July 10, 2018.

Dated: September 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-20288 Filed: 9/17/2018 8:45 am; Publication Date: 9/18/2018]