



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

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

DSM Biomedical; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by DSM Biomedical, proposing that the color additive regulations be amended to provide for the safe use of high purity carbon black for coloring ultra-high molecular weight polyethylene sutures for use in general surgery.

DATES: The color additive petition was filed on January 27, 2017.

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, 301-796-9465.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 7C0310), submitted by DSM Biomedical, 735 Pennsylvania Dr., Exton, PA 19341. The petition proposes to amend the color additive regulations in 21 CFR part 73, Listing of Color Additives Exempt From Certification, to provide for the safe use of high purity carbon black for coloring ultra-high molecular weight polyethylene sutures for use in general surgery.

We have determined under 21 CFR 25.32(l) 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.

Dated: February 28, 2017.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

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