

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Airbus Defence and Space Technical Document DT-86-3001, CN-235 Airworthiness Limitations List, Issue R, dated March 20, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus Defense and Space, Services/Engineering Support, Avenida de Aragón 404, 28022 Madrid, Spain; telephone: +34 91 585 55 84; fax: +34 91 585 31 27; email: MTA.TechnicalService@airbus.com.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on November 29, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018-26621 Filed 12-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2017-C-2902]

Listing of Color Additives Subject to Certification; D&C Yellow No. 8; 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 October 26, 2018, for the final rule that appeared in the **Federal Register** of September 25, 2018, and that amended the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

DATES: The effective date of final rule published in the **Federal Register** of September 25, 2018 (83 FR 48373) is confirmed: October 26, 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:

Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 2018 (83 FR 48373), we amended the color additive regulations to add § 74.3708, "D&C Yellow No. 8," (21 CFR 74.3708) to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

We gave interested persons until October 25, 2018, to file objections or requests for a hearing. We explained that, to file an objection, among other things, persons must specify with particularity the provision(s) to which they object. We also explained that if a person who properly submits an objection wants a hearing, he or she must specifically request a hearing and that failure to do so will constitute a waiver of the right to a hearing (83 FR 48373 at 48375).

We received seven comments regarding our decision to amend the color additive regulations to provide for the expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution. None of the comments, however, specified with particularity the provision(s) of the regulation to which they objected nor specifically requested a hearing. Therefore, we find that the effective date of the final rule that published in the **Federal Register** of September 25, 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 September 25, 2018, final rule. Accordingly, the amendments issued in the final rule became effective October 26, 2018.

Dated: December 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-27234 Filed 12-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA-2013-N-1529]

RIN 0910-AH75

Medical Device Classification Procedures: Incorporating Food and Drug Administration Safety and Innovation Act Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its regulations governing classification and reclassification of medical devices to conform to the applicable provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA). FDA is also making additional changes unrelated to the FDASIA requirements, to update its regulations governing the classification and reclassification of medical devices. FDA is taking this action to codify the procedures and criteria that apply to the classification and reclassification of medical devices and to provide for classification of devices in the lowest regulatory class consistent with the public health and the statutory scheme for device regulation.

DATES: This rule is effective March 18, 2019.

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For information concerning the final rule as it relates to devices regulated by the Center for Devices and Radiological Health (CDRH): Ana Loloei, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5452, Silver Spring, MD 20993-0002.

For information concerning the final rule as it relates to devices regulated by the Center for Biologics Evaluation and Research (CBER): Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire