§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):


(a) Effective Date

This AD becomes effective December 6, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to certain Arriel 1, 1A, 1A1, 1A2, 1B, 1B2, 1C, 1C1, 1C2, 1D, 1D1, 1E, 1E2, 1K1, 1S, and 1S1 turboshaft engines, with modification TU376 installed.

(d) Reason

This AD was prompted by an anomaly that occurred during the grinding operation required by modification TU376, which increases the clearance between the rear curvilinear coupling of the centrifugal impeller and the fuel injection manifold. We are issuing this AD to prevent failure of the centrifugal impeller, uncontained centrifugal impeller release, damage to the engine, and damage to the helicopter.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Remove from service, any centrifugal impeller listed in Table 1 to paragraph (e) of this AD, before exceeding the applicable cycles since new (CSN) and replace with a new turbine impeller.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: ANE-AD-AMOC@faa.gov.

(g) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: philip.haberlen@faa.gov.


(h) Material Incorporated by Reference

None.

Issued in Burlington, Massachusetts, on October 24, 2016.

Colleen M. D’Alessandro, Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–26184 Filed 10–31–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 74

[Docket No. FDA–2016–F–0821]

Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-) Copper]

AGENCY: Food and Drug Administration, HHHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for intraocular lenses. This action is in response to a petition filed by Milton W. Chu, M.D.

DATES: This rule is effective December 2, 2016. See section IX for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by December 1, 2016.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions

Submit electronic objections in the following way:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on http://www.regulations.gov.

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2016–F–0821 for “Listing of Color Additives Exempt From Certification; Titanium Dioxide and Listing of Color Additives Subject to Certification; [Phthalocyaninato (2-)] Copper.” Received objections will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper

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submittion. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:
I. Introduction
In a document published in the Federal Register of March 22, 2016 (81 FR 15173), we announced that we had filed a color additive petition (CAP 6C0305), submitted by Milton W. Chu, M.D. (petitioner), 5800 Santa Rosa Rd., Suite 111, Camarillo, CA 93012. The petition proposed to amend the color additive regulations in § 73.3126 (21 CFR 73.3126) and § 74.3045 (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for intraocular lenses (IOLs). IOLs are devices made of materials such as glass or plastic and are intended to be implanted to replace the natural lens of an eye (21 CFR 886.3600). The orientation marks are intended to aid the surgeon in visualization and placement of IOLs during lens implantation surgery. Because IOLs are permanently implanted, titanium dioxide and [phthalocyaninato (2-)] copper, in the colored orientation marks, will come into direct contact with a patient’s eye for a significant amount of time. These color additives are, therefore, subject to section 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e).

II. Background
Titanium dioxide is already approved as a color additive for foods (§ 73.575), drugs (§ 73.1575), cosmetics (§ 73.2575), and medical devices (§ 73.3126). Regarding its use in medical devices, titanium dioxide (CAS Reg. No. 13463–67–7, Color Index No. 77891) is currently approved under § 73.3126(b)(1) for use as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect and must meet the identity and specification requirements in § 73.575(a)(1) and (b). Titanium dioxide is exempt from certification under section 721(c) of the FD&C Act because we previously determined that certification was not necessary for the protection of public health (51 FR 24815, July 9, 1986).

[Phthalocyaninato (2-)] copper (CAS Reg. No. 147–14–8, Color Index No. 74160) is currently approved as a color additive under § 74.3045(c)(1) for use in coloring certain non-absorbable sutures for general and ophthalmic surgery, and for use in coloring specific monofilament sutures as supporting side struts (haptics) that hold the IOLs in place in the eye, at a level up to 0.5 percent by weight of the suture or haptic material. In addition, it is currently approved as a color additive under § 74.3045(c)(2) for use in coloring contact lenses in amounts not to exceed the minimum amount reasonably required to accomplish the intended coloring effect. We previously determined that batch certification was necessary to ensure the safety of [phthalocyaninato (2-)] copper (34 FR 6777, April 23, 1969).

III. Safety Evaluation
A. Determination of Safety
Under section 721(b)(4) of the FD&C Act, a color additive may not be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. Our color additive regulations at 21 CFR 70.3(i) define “safe” to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive. To establish with reasonable certainty that these color additives intended to color IOL orientation marks are not harmful under their intended conditions of use, we considered exposure to the additives and their impurities, each additive’s toxicological data, and other relevant information (such as published literature) available to us.

B. Safety of Petitioned Use of the Color Additives
Regarding the petitioned use, titanium dioxide and [phthalocyaninato (2-)] copper are intended to color orientation marks for IOL materials (polymers) to create white and translucent or opaque blue marks that are typically 100–250 microns (μm) in diameter and 80–150 μm in depth. Titanium dioxide will be used in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect of the orientation marks.

[Phthalocyaninato (2-)] copper will be used at levels not to exceed 0.5 percent by weight of the orientation marks.

To assess safety, we compared an individual’s estimated exposure to these two color additives for the petitioned use to color orientation marks to the approved uses of these color additives, including in IOL haptics and opaque contact lenses, because these uses are similar. As part of our previous approval for titanium dioxide used to color contact lenses, we estimated exposure to titanium dioxide from this use to be 270 nanograms per person per day (ng/p/d) over the lens lifetime (51 FR 24815), which does not significantly contribute to the cumulative exposure when compared to the exposure to titanium dioxide from the approved uses of mica-based pearlescent pigments (of which titanium dioxide is a component) in food and pharmaceuticals (Ref. 1). Similarly, we previously estimated exposure to [phthalocyaninato (2-)] copper from the use of surgical sutures, contact lenses, and specific monofilaments used as supporting haptics for IOLs to be 310 ng/p/d, 280 ng/p/d, and 0.3 ng/p/d, respectively (64 FR 23185, April 30, 1999; 51 FR 39370, October 28, 1986; and 52 FR 15944, May 1, 1987). With respect to the petitioned use, we estimated that the worst-case lifetime exposure to titanium dioxide and [phthalocyaninato (2-)] copper used to color orientation marks would be no greater than 0.06 ng/p/d and 0.004 ng/
IV. Conclusion

Based on the data and information in the petition and other relevant material, we conclude that the petitioned use of titanium dioxide and [phthalocyaninato (2-)] copper to color orientation marks for IOLs is safe. We further conclude that these additives will achieve their intended technical effect and are suitable for the petitioned use. Consequently, we are amending the color additive regulations in parts 73 and 74 as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we conclude that certification of titanium dioxide remains unnecessary for the protection of the public health. We also conclude that batch certification of [phthalocyaninato (2-)] copper continues to be necessary to protect the public health.

V. Public Disclosure and Confidentiality of Data and Information in a Color Additive Rule

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see FOR FURTHER INFORMATION CONTACT). As provided in § 71.15, we will delete from the petition and the documents any materials that are not available for public disclosure.

VI. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the March 22, 2016, notice of petition for CAP 6C0305 (81 FR 15173). We stated that we had 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” such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

This rule is effective as shown in the DATES section except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) of the regulation to which you object and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. We will publish notice of the objections that we have received or lack thereof in the Federal Register.

IX. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at http://www.regulations.gov.


List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 74

Color additives, Cosmetics, Drugs. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and re-delegated to the Director, Center for Food Safety and


PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for part 73 continues to read as follows:


2. In § 73.3126, revise paragraph (b)(1) to read as follows:

§ 73.3126 Titanium dioxide.

(b) * * * (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses and intraocular lens orientation marks in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect. * * * * *

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

3. The authority citation for part 74 continues to read as follows:


4. In § 74.3045, revise paragraphs (c)(1) introductory text and (c)(1)(i) to read as follows:

§ 74.3045 [Phthalocyaninato (2-)] copper.

(c) * * * (1) The color additive [phthalocyaninato(2-)] copper may be safely used to color polypropylene sutures, polybutester (the generic designation for the suture fabricated from 1,4-benzenedicarboxylic acid, polymer with 1,4-butanediol and alpha-hydro-omega-hydroxypoly(oxy-1,4-butanediyl)], CAS Reg. No. 37282–12–5) nonabsorbable sutures for use in general and ophthalmic surgery, polybutylene terephthalate nonabsorbable monofilament sutures for general and ophthalmic surgery, nonabsorbable sutures made from poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene) for general and ophthalmic surgery, polyvinylidene chloride monofilament used as supporting haptics for intraocular lenses, and polymers used in orientation marks for intraocular lenses, subject to the following restrictions:

(i) The quantity of the color additive does not exceed 0.5 percent by weight of the suture, haptic material, or orientation mark. * * * * *