§ 39.13 [Amended]

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

2016–22–10 Turbomeca S.A.: Amendment 39–186990; Docket No. FAA–2016–6990; Directorate Identifier 2016–NE–14–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 curvic 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 centrifugal impeller not listed in Table 1 to paragraph (e) of this AD.

TABLE 1 TO PARAGRAPH (e)—CENTRIFUGAL IMPELLER CSNS

Part No.	Serial No.	CSN
0292254040	44	5,129
0292254040	1762FT	11,476
0292254050	1676CAR	6,281
0292254050	5333OTT	5,495
0292254050	5017OTT	5,491
0292254050	1136CAR	8,734
0292254050	3655OTT	4,600
0292254050	1757CAR	7,913
0292254050	1738CAR	10,640
0292254050	1149CAR	12,273
0292254050	2677OTT	11,145
0292254050	3109OTT	10,662
0292254050	3496OTT	5,562
0292254050	2074CAR	7,423
729225293A	290CAR	6,326
729225293A	1227FT	8,139
729225293A	504FB	4,600
729225293A	2517OTT	9,732
729225293A	2165OTT	6,163
729225293A	2194FT	11,461
729225293A	1331OTT	12,513
729225293A	1301FT	7,262
729225293A	1567FT	6,305
729225293A	783FB	8,307
729225293A	98OTT	9,492

(2) Reserved.

(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.*

(2) Refer to MCAI, European Aviation Safety Agency AD 2016–0090, dated May 10, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2016–6990.

(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, HHS.

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

submission. 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 and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1275.

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 monofilaments used 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 IOL 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/

p/d, respectively, over a 70-year lifetime (Ref. 2). This exposure estimate is conservative as it assumes 100 percent migration of the color additives from the IOLs into the ocular fluid of the eye over a lifespan of 70 years following lens implantation. However, we expect that the color additives in the orientation marks will most likely be either chemically bound or otherwise integrated into the lens material, which would limit migration of the color additives into the ocular fluid of the eye. This means that the actual exposures to titanium dioxide and [phthalocyaninato (2-)] copper to color IOL orientation marks are expected to be far less than the worst-case exposure estimates for these color additives and insignificant in comparison to the cumulative exposures from the other approved uses of these color additives that we have already established to be safe (Ref. 2).

In assessing biocompatibility and toxicity of IOLs, we consider the International Standard for intraocular lens testing for biocompatibility (ISO 11979–5) as an appropriate standard. In general, ISO 11979–5 recommends investigations on the following biological endpoints: Cytotoxicity, genotoxicity, local effects after implantation, and sensitization potential, in the context of physicochemical properties.

The petitioner conducted a cytotoxicity study in which cultured cells were exposed to a mixture of titanium dioxide and [phthalocyaninato (2-)] copper in direct contact for at least 24 hours. Both color additives were found to be noncytotoxic in this study. Cytotoxicity studies of [phthalocyaninato (2-)] copper in previous petitions also indicated no cytotoxicity (Ref. 3). Additionally, the toxicology data for [phthalocyaninato (2-)] copper from previous petitions, as well as relevant data found in the Organization for Economic Cooperation and Development's Screening Information Dataset (OECD's SIDS) database, all indicated negative results for genotoxicity, carcinogenicity, implantation safety, and sensitization potential (Ref. 3). Similarly, data on titanium dioxide in OECD's SIDS database reported negative results for genotoxicity and sensitization potential. We conclude that the available toxicology data are sufficient to support the safety of the proposed expanded uses of titanium dioxide and [phthalocyaninato (2-)] copper.

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 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.*

1. Memorandum from H. Lee, Division of Petition Review, Chemistry Review Team, to P. DeLeo, Division of Petition Review, Regulatory Group I, FDA, March 1, 2005.
2. Memorandum from H. Lee, Division of Petition Review, Chemistry Review Team, to L. Dye, Division of Petition Review, Regulatory Group I, FDA, April 20, 2016.
3. Memorandum from Y. Zang, Division of Petition Review, Toxicology Review Team, to L. Dye, Division of Petition Review, Regulatory Group I, FDA, June 30, 2016.

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

Applied Nutrition, 21 CFR parts 73 and 74 are amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

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

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 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:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 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, polymethylmethacrylate 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.

* * * * *

Dated: October 25, 2016.

Susan Bernard,

Director, Office of Regulations, Policy and Social Science, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–26310 Filed 10–31–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 117

[Docket No. FDA–2011–N–0920]

What You Need To Know About the Food and Drug Administration Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled ''What You Need To Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food''—Small Entity Compliance Guide. The small entity compliance guide (SECG) is intended to help small entities comply with the final rule titled ''Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.''

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 comments submitted to the Division of Dockets Management, FDA will post your comment, 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–2011–N–0920 for ''What You Need To Know About the FDA Regulation: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117).'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. 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