AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
25–Jun–15	OH	Cambridge	Cambridge Muni	5/7977	05/13/15	VOR–A, Amdt 4.
25–Jun–15	OH	Cambridge	Cambridge Muni	5/7979	05/13/15	LOC/DME Rwy 22, Amdt 1B.
25–Jun–15	OH	Cambridge	Cambridge Muni	5/7981	05/13/15	RNAV (GPS) Rwy 4, Orig-A.
25–Jun–15	OH	Tiffin	Seneca County	5/8225	05/12/15	NDB Rwy 24, Amdt 7B.
25–Jun–15	FL	Hollywood	North Perry	5/8526	05/13/15	RNAV (GPS) Rwy 10R, Orig-A.
25–Jun–15	FL	Hollywood	North Perry	5/8528	05/13/15	RNAV (GPS) Rwy 28R, Orig-A.
25–Jun–15	GA	Vidalia	Vidalia Rgnl	5/8557	05/08/15	ILS OR LOC/NDB Rwy 24, Amdt 1.
25–Jun–15	NM	Alamogordo	Alamogordo-White Sands Rgnl.	5/8653	05/13/15	VOR Rwy 3, Amdt 2A.
25–Jun–15	NM	Alamogordo	Alamogordo-White Sands Rgnl.	5/8654	05/13/15	RNAV (GPS) Rwy 3, Orig-A.
25–Jun-15	NM	Alamogordo	Alamogordo-White Sands Rgnl.	5/8655	05/13/15	VOR/DME Rwy 3, Orig-A.
25–Jun–15	TX	Nacogdoches	A L Mangham Jr Rgnl.	5/8755	05/13/15	ILS OR LOC Rwy 36, Amdt 3B.
25–Jun–15	MI	Sault Ste Marie	Chippewa County Intl	5/8758	05/12/15	ILS OR LOC Rwy 16, Amdt 8B.
25–Jun–15	IL	Chicago/Prospect Heights/Wheeling.	Chicago Executive	5/8761	05/13/15	ILS OR LOC Rwy 16, Amdt 2C.
25–Jun–15	OK	Tulsa	Tulsa Intl	5/8766	05/13/15	VOR/DME Rwy 8, Amdt 4A.
25–Jun–15	KY	Somerset	Lake Cumberland Rgnl.	5/8799	05/13/15	ILS OR LOC/DME Rwy 5, Orig-B.
25–Jun–15	KY	Somerset	Lake Cumberland Rgnl.	5/8800	05/13/15	RNAV (GPS) Y Rwy 5, Amdt 3.
25–Jun–15	MN	Ely	Ely Muni	5/9087	05/13/15	RNAV (GPS) Rwy 12, Amdt 1A.
25–Jun–15	MN	Silver Bay	Silver Bay Muni	5/9407	05/13/15	NDB Rwy 25, Orig.
25–Jun–15	MN	Silver Bay	Silver Bay Muni	5/9419	05/13/15	RNAV (GPS) Rwy 25, Orig.
25–Jun–15	TX	Weslaco	Mid Valley	5/9422	05/13/15	GPS Rwy 13, Orig-A.
25–Jun–15	TX	Weslaco	Mid Valley	5/9423	05/13/15	VOR/DME–A, Orig.
25–Jun–15	IL	Paxton	Paxton	5/9445	05/13/15	RNAV (GPS) Rwy 18, Orig.
25–Jun–15	IL	Paxton	Paxton	5/9446	05/13/15	VOR Rwy 18, Amdt 2.
25–Jun–15	LA	Winnfield	David G Joyce	5/9450	05/13/15	RNAV (GPS) Rwy 27, Orig.
25–Jun–15	LA	Winnfield	David G Joyce	5/9451	05/13/15	RNAV (GPS) Rwy 9, Orig-A.
25–Jun–15	IA	Chariton	Chariton Muni	5/9553	05/13/15	RNAV (GPS) Rwy 10, Orig.
25–Jun–15	IA	Chariton	Chariton Muni	5/9554	05/13/15	RNAV (GPS) Rwy 17, Amdt 1A.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9719	05/13/15	ILS OR LOC Rwy 21L, Amdt 19.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9720	05/13/15	NDB Rwy 21L, Amdt 17A.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9721	05/13/15	RNAV (GPS) Rwy 21L, Amdt 1B.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9722	05/13/15	NDB Rwy 25, Amdt 12A.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9723	05/13/15	LOC BC Rwy 3R, Amdt 8D.
25–Jun–15	OH	Cincinnati	Cincinnati Muni Airport Lunken Field.	5/9724	05/13/15	RNAV (GPS) Rwy 25, Amdt 1A.

[FR Doc. 2015–13824 Filed 6–5–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket Nos. FDA–2014–C–1616 and FDA–2015–C–0245]

Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments

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 mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes, and in egg decorating kits for coloring shell eggs. This action is in response to two color additive petitions (CAPs) submitted separately by EMD Millipore Corp. and by Signature Brands, LLC.

DATES: This rule is effective July 9, 2015. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by July 8, 2015.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA–2014–C–1616 (Mica-based pearlescent pigments in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes) or Docket No. FDA–2015–C–0245 (Mica-based pearlescent pigments in egg decorating kits), by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2014–C–1616 (Mica-based pearlescent pigments in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, non-alcoholic cocktail mixers and mixes) or Docket No. FDA–2015–C–0245 (Mica-based pearlescent pigments in egg decorating kits) for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket numbers, 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: Ellen Anderson, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1309.

SUPPLEMENTARY INFORMATION:

I. Background

In notices published in the **Federal Register** on October 21, 2014, and February 5, 2015 (79 FR 62932 and 80 FR 6468, respectively), we announced that we filed CAPs (4C0299 and 5C0301, respectively) to amend the color additive regulations in § 73.350 *Mica-based pearlescent pigments* (21 CFR 73.350).

CAP 4C0299 was submitted by EMD Millipore Corp. (EMD), c/o Hyman, Phelps & McNamara, P.C., 700 13th St. NW., Suite 1200, Washington, DC 20005. CAP 4C0299 proposed to amend the color additive regulations in § 73.350 to expand the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as a color additive in cordials, liqueurs, cocktails, and certain other alcoholic beverages, and non-alcoholic cocktail mixers and mixes. The maximum use level of the pigments proposed by the petitioner is 0.07 percent by weight in the beverages, mixers, and mixes, consistent with approval in § 73.350(c)(1)(ii) for the use of mica-based pearlescent pigments in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume, but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis. In correspondence with FDA, EMD subsequently refined the petitioned use of mica-based pearlescent pigments to cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixers and mixes.

CAP 5C0301 was submitted by Signature Brands, LLC, c/o Keller and Heckman, LLP, 1001 G St. NW., Suite 500 West, Washington, DC 20001. CAP 5C0301 proposed to amend § 73.350 to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica in egg decorating kits for coloring boiled shell eggs, in amounts consistent with good manufacturing practice (GMP).

Mica-based pearlescent pigments prepared from titanium dioxide and mica are currently approved under § 73.350(c)(1)(i) for use as a color additive in amounts up to 1.25 percent by weight in cereals, confections and frostings, gelatin deserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum. Mica-based pearlescent pigments prepared from titanium dioxide and mica are also currently approved under § 73.350(c)(1)(ii) in amounts up to 0.07 percent, by weight, in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume, but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis. Mica-based pearlescent pigments prepared from titanium dioxide on mica, iron oxide on mica, and titanium dioxide and iron oxide on mica are approved for specified uses as a color additive in ingested drugs under § 73.1350 (21 CFR 73.1350). Mica-based pearlescent pigments formed by depositing titanium or iron salts from a basic solution onto mica, followed by calcination to produce titanium dioxide or iron oxides on mica, are approved for specified uses in contact lenses under § 73.3128 (21 CFR 73.3128). The color additive that is the subject of the two color additive petitions at issue, mica-based pearlescent pigments prepared from titanium dioxide and mica, will be referred hereinafter in this final rule as mica-based pearlescent pigments.

II. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. FDA's color additive regulations in 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 a color additive intended for use in food is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated daily intake (EDI) of the additive from all food sources to an acceptable daily intake (ADI) established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all food sources of the additive. We typically use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic dietary exposure.

B. Petitioned Uses of the Color Additive

In CAP 4C0299, EMD proposed to amend the color additive regulations in § 73.350 to provide for the safe use of mica-based pearlescent pigments as a color additive in amounts up to 0.07 percent, by weight, in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixes and mixers. According to the standards of identity for distilled spirits regulations issued by the Alcohol and Tobacco Tax and Trade Bureau (TTB), which regulates the labeling of certain alcoholic beverages, cordials and liqueurs are a class of distilled spirits obtained by mixing or redistilling distilled spirits with or over fruits, flowers, plants, or pure juices therefrom, or other natural flavoring materials, or with extracts derived from infusions, percolation, or maceration of such materials, and containing sugar, dextrose, or levulose, or a combination thereof, in an amount not less than 2½ percent by weight of the finished product (27 CFR 5.22(h)). Neither FDA nor TTB has a regulatory definition for ''cocktail.'' The petition defines cocktails as ''products that are sold as mixtures of distilled spirits and non-alcoholic ingredients.'' Subsequent communication with the petitioner clarified that the following are descriptions of the types of cocktail products included within the scope of the petition: (1) Cocktails containing

one or more alcoholic beverages and one or more non-alcoholic mixers (*e.g.,* margarita, gin and tonic, cosmopolitan, fuzzy navel, Bloody Mary, caipirinha, Irish coffee, Long Island iced tea, daiquiri, hurricane); (2) cocktails containing one or more alcoholic beverages without non-alcoholic mixers (*e.g.,* vodka martini, stinger, black Russian, Manhattan); (3) cocktails containing beer (*e.g.,* caipbeerinha, boilermaker, beer Bloody Mary); (4) cocktails containing wine (*e.g.,* mimosa, Kir Royale, wine cooler, wine spritzer); and (5) non-alcoholic mixes and mixers for use in cocktails (*e.g.,* margarita mix, daiquiri mix, Bloody Mary mix). We note that mica-based pearlescent pigments are intended to be used in both liquid and powdered forms of non-alcoholic cocktail mixes and mixers, at a maximum use level of 0.07 percent by weight of the mix or mixer (Ref. 1). Furthermore, only non-alcoholic mixes and mixers that are marketed specifically for use in cocktails, such as margarita mix and Bloody Mary mix, are included within the scope of this petition (Ref. 1). Beverages that are typically consumed without added alcohol (*e.g.,* fruit juices, carbonated water, soft drinks) are outside the scope of this petition. The petition also proposed to amend § 73.350 to provide for the safe use of mica-based pearlescent pigments in flavored alcoholic malt beverages and wine coolers. Like ''cocktail,'' the term ''wine cooler'' does not have a regulatory definition. According to TTB, products traditionally known as wine coolers have generally been replaced in recent years by flavored alcoholic malt beverages, which are manufactured with a malt base rather than with wine (Ref. 1). Flavored alcoholic malt beverages are sold under many proprietary names and include alcoholic lemonades, alcoholic colas, and other flavored alcoholic beverages (see 70 FR 194 at 195 (January 3, 2005) (TTB final rule pertaining to ''Flavored Malt Beverage and Related Regulatory Amendments'')). Products marketed as wine coolers and flavored alcoholic malt beverages are included in the scope of the petition to amend the color additive regulations in § 73.350. Traditional malt beverages, such as beer, ale, and malt liquor, differ substantially from flavored alcoholic malt beverages (see 70 FR 194) and are not included within the scope of the petition. Wine, which has a standard of identity defined under TTB's regulations at 27 CFR part 4, subpart C, is also outside the scope of the petition. Furthermore, the petitioner clarified that the scope of the petition does not include sangria, which is typically a mixture of wine, fruit, and other ingredients.

In CAP 5C0301, Signature Brands, LLC proposed to amend the color additive regulations in § 73.350 to provide for the safe use of mica-based pearlescent pigments as a color additive in egg decorating kits to color the shells of boiled eggs in amounts consistent with GMP. The petitioner proposed to use mica-based pearlescent pigments in a packet of glaze that is part of egg decorating kits sold for in-home use. According to the kit instructions, the glaze containing the mica-based pearlescent pigments is intended to be rubbed on the shells of colored boiled eggs to impart a metallic sheen.

C. Safety of the Petitioned Uses of the Color Additive

During our safety review of the uses of mica-based pearlescent pigments proposed in CAPs 4C0299 and 5C0301, we considered the exposure to the color additive from its petitioned uses and from the currently permitted uses in food and ingested drugs under §§ 73.350 and 73.1350, respectively. In estimating the cumulative estimated dietary intake (CEDI) of these pigments, we determined that the exposure to mica-based pearlescent pigments from the use in contact lenses (§ 73.3128) is negligible and, therefore, need not be included in our exposure estimate. Furthermore, we concluded that the exposure to the additive from the petitioned use in coloring the shells of boiled eggs is also negligible. In CAP 5C0301, the petitioner noted that, because eggshells are not consumed, exposure to mica-based pearlescent pigments would be limited to the amount of additive that migrates through the shell and the inner membrane that separates the shell from the edible egg. The petitioner asserted that, given the pigments' relatively large particle size and insolubility in food, the amount of mica-based pearlescent pigments that could actually be found in the edible portion of the egg is insignificant. The petitioner provided a conservative estimate for potential exposure to the additive from the petitioned use based on a worst-case scenario that presumed the theoretical maximum solubility of mica-based pearlescent pigments is equivalent to that of mica (80 milligrams/kilograms in 10 percent acetic acid). Exposure to mica-based pearlescent pigments from decorated eggshells is likely further reduced by the typically limited seasonal availability of the egg decorating kits. We agree with the rationale proposed in CAP 5C0301 that the exposure to the additive from the petitioned use is negligible, and that the petitioned use would not result in a significant contribution to the CEDI for mica-based pearlescent pigments (Ref. 2).

We estimate the eaters-only exposure to mica-based pearlescent pigments from the proposed uses in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixers and mixes for the U.S. population to be 0.15 grams/person/day (g/p/d) at the mean and 0.34 g/p/d at the 90th percentile (Ref. 1). (An eaters-only exposure is the total of the amount of food consumed per day averaged over the number of days in the survey period by individuals consuming the food at least once during the survey period.) In a previous amendment to § 73.350 (78 FR 35115 at 35115 and 35116 (June 12, 2013)), we estimated a CEDI for the use of mica-based pearlescent pigments in food (§ 73.350) and ingested drugs (§ 73.1350) using food consumption data from the 2003 to 2008 National Health and Nutrition Examination Survey (NHANES). In our current safety assessment, we updated the previous exposure to mica-based pearlescent pigments from all approved uses in foods using NHANES food consumption data from 2007 to 2010. In estimating the exposure to mica-based pearlescent pigments from the use in ingested drugs, we relied on the estimates used in a previous safety evaluation (Ref. 1). The updated eaters-only CEDI of mica-based pearlescent pigments, including the petitioned use in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixers and mixes, and the currently approved uses in food and ingested drugs, is 0.25 g/p/d at the mean and 0.50 g/p/d at the 90th percentile for the U.S. population (Ref. 1). The updated CEDIs for mica-based pearlescent pigments are not significantly different from the previous CEDIs (78 FR 35115 at 35116). This is not unexpected, as both the previous and updated exposure estimates were based on a similar set of NHANES food codes that included cordials, liqueurs, and cocktails (Ref. 1). In addition, the percent of the population consuming alcoholic beverages from the petitioned use is significantly lower compared to the proportion of the population that consumes foods and ingested drugs containing mica-based pearlescent pigments, thereby resulting in a smaller contribution to the CEDI (Ref. 1).

To support the safety of the proposed uses of mica-based pearlescent pigments in food, the petitioners of CAPs 4C0299 and 5C0301 referenced the safety

determination made by FDA for previously filed petitions (70 FR 42271 (July 22, 2005); 71 FR 31927 (June 2, 2006); and 78 FR 35115). In a prior safety evaluation, we concluded that the bioavailability of ingested mica-based pearlescent pigments and/or their individual components is expected to be low based on the chemical nature of these inorganic pigments and their individual components and the low solubility of mica-based pearlescent pigments in media relevant to human health (*e.g.,* digestive fluids in the gastrointestinal tract) (70 FR 42271 at 42272). We are not aware of any new studies on the bioavailability of mica-based pearlescent pigments published since our previous evaluation (70 FR 42271). As part of our current safety evaluation, we also reviewed several recent studies on titanium dioxide, which is a component of mica-based pearlescent pigments, to further clarify the extent of the color additive's bioavailability. We determined that the new information on titanium dioxide supports our previous conclusion that mica-based pearlescent pigments are not bioavailable to any significant extent upon ingestion (Ref. 3).

In our previous safety evaluation, which the petitioners referenced, we established an ADI for mica-based pearlescent pigments to be 1.8 g/p/d based on a 2-year rat carcinogenicity bioassay (71 FR 31927 at 31928). Since the updated CEDI (0.50 g/p/d at the 90th percentile) for mica-based pearlescent pigments for the U.S. population is less than the ADI, we conclude that the proposed expanded use of mica-based pearlescent pigments as a color additive at levels of up to 0.07 percent by weight in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixers and mixes is safe (Ref. 3). We also conclude that the proposed expanded use of mica-based pearlescent pigments in egg decorating kits to color the shells of eggs at levels consistent with GMP is safe, since the exposure to mica-based pearlescent pigments contributed by this use is negligible (Ref. 3).

III. Conclusion

Based on the data and information in the petitions and other relevant material, FDA concludes that the petitioned use of mica-based pearlescent pigments prepared from titanium dioxide and mica as a color additive at levels of up to 0.07 percent by weight in cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, cocktails, and non-alcoholic cocktail mixers and mixes is safe. We also conclude that the petitioned use of mica-based pearlescent pigments prepared from titanium dioxide and mica as a color additive in egg decorating kits used to color the shells of eggs in amounts consistent with GMP is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned uses. Therefore, we are amending the color additive regulations in part 73 (21 CFR part 73) 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-coated mica-based pearlescent pigments is not necessary for the protection of the public health.

IV. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petitions and the documents that we considered and relied upon in reaching our decision to approve the petitions 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.

V. Environmental Impact

We previously considered the environmental effects of this rule, as stated in the October 21, 2014, and February 5, 2015, notices of filing for CAPs 4C0299 and 5C0301 (79 FR 62932 and 80 FR 6468, respectively). For CAP 4C0299, we stated that we had determined, under 21 CFR 25.32(k), 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. For CAP 5C0301, we stated that we had determined, under § 25.32(r), 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 determinations.

VI. 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.

VII. Section 301(*ll*) of the Federal Food, Drug, and Cosmetic Act

Our review of these petitions was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(*ll*)(1) to (4) of the FD&C Act applies. In our review of these petitions, we did not consider whether section 301(*ll*) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(*ll*) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(*ll*) of the FD&C Act applies.

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) 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.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the

heading of this document. 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 have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. FDA Memorandum from H. Lee, Chemistry Review Group, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, January 5, 2015.
2. FDA Memorandum from H. Lee, Chemistry Review Group, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, March 13, 2015.
3. FDA Memorandum from S. Park, Toxicology Team, Division of Petition Review, to E. Anderson, Regulatory Group II, Division of Petition Review, March 18, 2015.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR 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. Section 73.350 is amended by revising paragraph (c)(1)(ii) and by adding paragraph (c)(1)(iii) to read as follows:

§ 73.350 Mica-based pearlescent pigments.

* * * * *

(c) * * *

(1) * * *

(ii) In amounts up to 0.07 percent, by weight, in the following:

(A) Distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis.

(B) Cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, and cocktails.

(C) Non-alcoholic cocktail mixes and mixers, such as margarita mix, Bloody Mary mix, and daiquiri mix, but excluding eggnog, tonic water, and beverages that are typically consumed without added alcohol (*e.g.,* fruit juices, fruit juice drinks, and soft drinks).

(iii) In egg decorating kits used for coloring the shells of eggs in amounts consistent with good manufacturing practice.

* * * * *

Dated: June 2, 2015.

Susan Bernard,

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

[FR Doc. 2015–13834 Filed 6–5–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. FDA–2013–N–1518]

Cardiovascular Devices; Reclassification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Cardiopulmonary and Circulatory Bypass; Effective Date of Requirement for Premarket Approval for Nonroller-Type Cardiopulmonary Bypass Blood Pumps for Temporary Ventricular Support

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify nonroller-type cardiopulmonary bypass blood pump (NRP) devices for cardiopulmonary and circulatory bypass, a preamendments class III device, into class II (special controls), and to require the filing of a premarket approval application (PMA) for NRP devices for temporary ventricular support. FDA is also revising the title and identification of the regulation for NRP devices in this order.

DATES: This order is effective June 8, 2015.

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SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee) (the Panel); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as ''postamendments devices''), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new