DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2015–C–1154]

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 certain distilled spirits. This action is in response to a color additive petition (CAP) submitted by E. & J. Gallo Winery.

DATES: This rule is effective November 2, 2015. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by October 30, 2015.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA–2015–C–1154, 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 or 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–2015–C–1154 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 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: Salome Bhagan, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–3041.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** on April 22, 2015 (80 FR 22449), we announced that we filed a color additive petition (CAP 5C0302) to amend the color additive regulations in § 73.350 *Mica-based pearlescent pigments* (21 CFR 73.350).

CAP 5C0302 was submitted by E. & J. Gallo Winery, c/o Keller and Heckman LLP, Three Embarcadero Center, Suite 1420, San Francisco, CA 94111 (petitioner). In CAP 5C0302, E. & J. Gallo Winery proposed to amend the color additive regulations in § 73.350 to increase the maximum permitted alcohol content of distilled spirits to which mica-based pearlescent pigments may be added from 23 percent to 25 percent alcohol by volume, and to remove the current limitation for distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis. The term ''distilled spirits'' is defined by the Alcohol and Tobacco Tax and Trade Bureau as ethyl alcohol, hydrated oxide of ethyl, spirits of wine, whisky, rum, brandy, gin, and other distilled spirits, including all dilutions and mixtures thereof, for nonindustrial use. The term does not include mixtures containing wine, bottled at 48 degrees of proof or less, if the mixture contains more than 50 percent wine on a proof gallon basis (27 CFR 5.11).

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. They are also 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 (§ 73.350(c)(1)(ii)(A)); cordials, liqueurs, flavored alcoholic malt beverages, wine coolers, and cocktails (§ 73.350(c)(1)(ii)(B)); and 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) (§ 73.350(c)(1)(ii)(C)). The pigments also are approved under § 73.350(c)(1)(iii) in egg decorating kits used for coloring the shells of eggs in amounts consistent with good manufacturing practice. 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 use 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 use in contact lenses under § 73.3128 (21 CFR 73.3128). The color additive that is 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 establishes 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 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 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. Safety of the Petitioned Use of the Color Additive

During our safety review of the use of mica-based pearlescent pigments proposed in CAP 5C0302, we considered the exposure to the color additive from its petitioned use 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 egg decorating kits used for coloring the shells of boiled eggs and in contact lenses (§§ 73.350(c)(1)(iii) and 73.3128, respectively) is negligible and, therefore, does not contribute to the exposure.

The petitioner estimated the eaters-only exposure to mica-based pearlescent pigments from the proposed use in distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume at 0.14 grams per person per day (g/p/d) at the mean and 0.31 g/p/d at the 90th percentile for the U.S. population (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.) We conclude that the petitioner's exposure estimates are sufficiently conservative to account for the petitioned use of mica-based pearlescent pigments. Regarding cumulative exposure from the current and petitioned uses of mica-based pearlescent pigments, we note that in our recent final rule that provided for the safe use of mica-based pearlescent pigments 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, we estimated the CEDI for the use of mica-based pearlescent pigments in food (§ 73.350) and ingested drugs (§ 73.1350) to be 0.25 g/p/d at the mean and 0.50 g/p/d at the 90th percentile for the U.S. population (80 FR 32303 at 32305, June 8, 2015). Since the petitioned use of mica-based pearlescent pigments will generally substitute for currently-permitted uses of mica-based pearlescent pigments in other alcoholic beverages with no change in the maximum use level of 0.07 percent by weight, we have determined that the petitioned use of mica-based pearlescent pigments will not result in an increase in consumer exposure to these pigments. Therefore, we conclude that our previous CEDI for mica-based pearlescent pigments of 0.25 g/p/d at the mean and 0.50 g/p/d at the 90th percentile for the U.S. population will remain unchanged (Ref. 1).

To support the safety of the proposed use of mica-based pearlescent pigments in food, the petitioner 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, June 12, 2013); including our previously established ADI for mica-based pearlescent pigments of 1.8 g/p/d based on a 2-year rat carcinogenicity bioassay (71 FR 31927 at 31928). Because there is no increase in the intake of mica-based pearlescent pigments beyond a level that has already been established as safe, FDA has no concerns regarding the petitioned use of mica-based pearlescent pigments in distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume (Ref. 2).

III. Conclusion

Based on the data and information in the petition 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 a level of up to 0.07 percent by weight in distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume, is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned use. Therefore, we are amending the color additive regulations in 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 mica-based pearlescent pigments prepared from titanium dioxide and mica 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 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.

V. Environmental Impact

We previously considered the environmental effects of this rule, as stated in the April 22, 2015 notice of filing for CAP 5C0302 (80 FR 22449). 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. We have not received any new information or comments that would affect our previous determination.

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 this petition 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 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 (ll)(4) of the FD&C Act applies. In our review of this petition, 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 S. Bhagan, Regulatory Group I, Division of Petition Review, May 19, 2015.
2. FDA Memorandum from S. Park, Toxicology Team, Division of Petition Review, to S. Bhagan, Regulatory Group I, Division of Petition Review, June 8, 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)(A) to read as follows:

§ 73.350 Mica-based pearlescent pigments.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

(A) Distilled spirits containing not less than 18 percent and not more than 25 percent alcohol by volume.

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Dated: September 25, 2015.

Susan Bernard,

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

[FR Doc. 2015–24795 Filed 9–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0155]

Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a small entity compliance guide and guidance for industry #120 entitled ''Veterinary Feed Directive Regulation Questions and Answers.'' This guidance aids industry in complying with the requirements of the Veterinary Feed Directive (VFD) final rule that published in the **Federal Register** on June 3, 2015. The purpose of this document is to describe the Veterinary Feed Directive requirements for veterinarians, feed manufacturers and other distributors, animal producers, and other parties involved in the distribution or use of medicated feed containing a Veterinary Feed Directive drug (VFD feed).

DATES: Submit either electronic or written comments on Agency 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–2010–N–0155 for ''Veterinary Feed Directive Regulation Questions and Answers; Small Entity Compliance Guide; Guidance for Industry; Availability.'' 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