significant rule for purposes of Executive Order 13526 and has not been reviewed by the Office of Management and Budget. As required by the Regulatory Flexibility Act, TVA certifies that these regulatory amendments will not have a significant impact on small business entities. Since this rule in non-substantive, it is being made effective September 25, 2018.

List of Subjects in 18 CFR Part 1301

Freedom of information, Government in the sunshine, Privacy, Protection of national security classified information.

For the reasons stated in the preamble, TVA amends 18 CFR part 1301 as follows:

PART 1301—PROCEDURES

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 5 U.S.C. 552 and 552a; 16 U.S.C. 831–831dd.

Subpart E—Protection of National Security Classified Information

■ 2. In § 1301.63, revise paragraph (a) to read as follows:

§ 1301.63 Senior agency official.

(a) The Executive Order requires that each agency that originates or handles classified information designate a senior agency official to direct and administer its information security program. TVA's senior agency official is the Director, TVA Police & Emergency Management.

* * * * *

■ 3. In § 1301.67, revise paragraph (c) to read as follows:

§ 1301.67 Mandatory review for declassification.

* * * * *

(c) Requests shall be in writing, and shall be sent to: Director, TVA Police & Emergency Management, Tennessee Valley Authority, 400 West Summit Hill Drive, Knoxville, TN 37902.

Todd M. Peney,

Director, TVA Police & Emergency Management, Tennessee Valley Authority.

[FR Doc. 2018–20828 Filed 9–24–18; 8:45 am]

BILLING CODE 8120–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2017–C–2902]

Listing of Color Additives Subject to Certification; D&C Yellow No. 8

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 expanded safe use of D&C Yellow No. 8 as a color additive in contact lens solution. We are taking this action in response to a color additive petition submitted by Glo Eyes, LLC.

DATES: This rule is effective October 26, 2018. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by October 25, 2018.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before October 25, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 25, 2018. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, 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–2017–C–2902 for ''Listing of Color Additives Subject to Certification; D&C Yellow No. 8.'' Received objections, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or with the Dockets Management Staff 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 our 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1075.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** of May 31, 2017 (82 FR 24912), we announced that we filed a color additive petition (CAP 7C0311) submitted by Glo Eyes, LLC (petitioner), 5501 Highway 199, suite 202, Fort Worth, TX 76114. The petition proposed to amend the color additive regulations in 21 CFR part 74, *Listing of Color Additives Subject to Certification* by expanding the permitted uses of D&C Yellow No. 8 (principally the disodium salt of fluorescein) to include use in coloring contact lens solution at a level not to exceed 0.044 percent in the contact lens solution. Because the colored contact lens solution is intended for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses and because D&C Yellow No. 8 in these colored contact lenses will come into direct contact with the user's eyes for a significant amount of time, this color additive is subject to section 721 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e).

II. Background

D&C Yellow No. 8 is currently approved under § 74.1708 (21 CFR 74.1708) for coloring externally applied drugs in amounts consistent with good manufacturing practice (GMP). D&C Yellow No. 8 is also approved under § 74.2708 (21 CFR 74.2708) for coloring externally applied cosmetics in amounts consistent with GMP. The regulations for D&C Yellow No. 8 require that all batches of the color additive be certified in accordance with regulations in part 80.

D&C Yellow No. 8 (CAS 518–47–8) is principally the disodium salt of fluorescein. In the subject petition, D&C Yellow No. 8 is proposed for use as a color additive in contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses for up to 12 hours. The treated lenses are to be used one time and then discarded. The treated contact lenses, when exposed to ultraviolet light, fluoresce a yellow-green color for cosmetic purposes. The treated color contact lenses are expected to be used for limited, celebratory, and special occasions, and not every day. The maximum intended use level of D&C Yellow No. 8 in the contact lens solution is 0.044 percent. The contact lens solution colored with D&C Yellow No. 8 is intended for distribution by prescription only and for use in accordance with the directions supplied. Based on data and information provided in the petition on the identity, properties, manufacturing process, and composition of the color additive, we have determined that the color additive meets the specifications for D&C Yellow No. 8 in § 74.1708 (Ref. 1).

III. Safety Evaluation

Under section 721(b)(4) of the FD&C Act (21 U.S.C. 379e(b)(4)), 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 § 70.3(i) (21 CFR 70.3(i)) define ''safe'' to mean that there is convincing evidence establishing with reasonable certainty that no harm will result from the intended use of the color additive.

As part of our safety evaluation of the color additive, we considered the projected human exposure to D&C Yellow No. 8 and any impurities resulting from the petitioned use of the color additive. We also considered results from ocular irritation, skin sensitization, oral mucosal irritation, acute systemic toxicity, and cytotoxicity studies that tested extracts from contact lenses soaked in contact lens solution colored with D&C Yellow No. 8.

A. Exposure Estimate

During our safety assessment of the use of D&C Yellow No. 8 in contact lens solution, we considered the estimated exposure to D&C Yellow No. 8 that would result from the petitioned use in amounts not to exceed 0.044 percent in contact lens solution. The petitioner determined that the theoretical maximum amount of D&C Yellow No. 8 that could be absorbed by, and potentially extracted from, a contact lens is 17 micrograms per lens (µg/lens). The petitioner considers 17 µg/lens or 34 µg/person/day (p/d) (for two lenses) to be a conservative estimate of the exposure to the color additive under the proposed use conditions (Ref. 1). FDA agrees with the petitioner's estimate. We note that the estimated exposure (17 µg/lens or 34 µg/p/d) represents a theoretical maximum amount of the color additive per use and is based on the worst-case assumption that all the water in the hydrogel-based soft contact lens is displaced by the colored contact lens solution. However, this exposure estimate is not an estimate of chronic daily exposure since the treated contact lenses are for occasional wear and not for everyday use. Furthermore, the actual exposure to D&C Yellow No. 8 from the petitioned use is expected to be lower than 17 µg/lens or 34 µg/p/d based on the amount of color additive extracted from the contact lenses soaked in the colored contact lens solution as indicated in the instructions for use (Ref. 1).

B. Safety of Petitioned Use of Color Additive

To establish that D&C Yellow No. 8 is safe for use in a contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses, the petitioner submitted toxicity studies including an ocular irritation test in rabbits, a Guinea pig maximization sensitization test, an oral mucosal irritation study in hamsters, an acute systemic toxicity test in mice, and a cytotoxicity test that tested extracts from representative contact lenses soaked in contact lens solution colored with D&C Yellow No. 8. The results of these studies indicate that the color additive is not an irritant to the skin, eyes or oral mucosa, is not a sensitizer, is not cytotoxic, and shows no systemic toxicity (Ref. 2). Therefore, we conclude that the available toxicology data are sufficient to support the safety of the proposed expanded safe use of D&C Yellow No. 8.

IV. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of D&C Yellow No. 8 for coloring contact lens solution intended for soaking disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses is safe. We further conclude that this color additive will achieve its intended technical effect and is suitable for the petitioned use. Consequently, we are amending the color additive regulations in 21 CFR part 74 as set forth in this document. We also conclude that batch certification of

D&C Yellow No. 8 continues to be necessary to protect the public health.

V. Public Disclosure

In accordance with § 71.15(a) (21 CFR 71.15(a)), 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 **ADDRESSES**). As provided in § 71.15(b), 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 May 31, 2017, **Federal Register** notice of filing for CAP 7C0311 (82 FR 24912). 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 electronic objections to this docket at *https://www.regulations.gov,* or written objections with the Dockets Management Staff (see **ADDRESSES**). 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.

Any objections received in response to the regulation may be seen in the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://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 with the Dockets Management Staff (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 *https://www.regulations.gov.*

1. Memorandum from H. Lee, Chemistry Review Team, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 3, 2018.
2. Memorandum from A. Khan, Toxicology Team, Division of Petition Review, OFAS, CFSAN, FDA to M. Harry, Division of Petition Review, OFAS, CFSAN, FDA, July 12, 2018.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of the Food and Drugs, 21 CFR part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

■ 1. 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.

■ 2. Add § 74.3708 to subpart D to read as follows:

§ 74.3708 D&C Yellow No. 8.

(a) *Identity and specifications.* The color additive D&C Yellow No. 8 shall conform in identity and specifications to the requirements of § 74.1708(a)(1) and (b).

(b) *Uses and restrictions.* (1) D&C Yellow No. 8 may be safely used for coloring contact lens solution for coloring disposable daily-wear hydrogel-based soft (hydrophilic) contact lenses at a level not to exceed 0.044 percent in the contact lens solution. Following excitation by ultraviolet light, the colored contact lenses fluoresce a yellow-green color. The contact lens solution colored with D&C Yellow No. 8 is distributed by prescription only and used in accordance with the supplied directions for use. Contact lens solutions containing D&C Yellow No. 8 are intended for use only for coloring contact lenses that are worn for infrequent, celebratory occasions, and not for regular or daily use.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens solution in which the color additive is used.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Certification.* All batches of D&C Yellow No. 8 shall be certified in accordance with regulations in part 80 of this chapter.

Dated: September 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20767 Filed 9–24–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–0619]

RIN 1625–AA00

Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters near New Orleans, LA, during a fireworks display on October 6, 2018. This regulation prohibits persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative.

DATES: This rule is effective from 9 p.m. through 10 p.m. on October 6, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://*