part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: 42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. In appendix 1 to subpart P of part 404:

■ a. In part A, amend section 1.00C7 by revising paragraphs a and c; and

■ b. In part B, amend section 101.00C7 by revising paragraphs a and c.

The revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

Part A

* * * * *

1.00 Musculoskeletal Disorders

* * * * *

C. * * *

7. * * *

a. The term *pandemic period* as used in 1.00C7c means the period beginning on April 2, 2021, and ending on May 11, 2025. The term *post-pandemic evaluation period* as used in 1.00C7c means the period beginning on May 12, 2025, and ending on May 11, 2029.

* * * * *

c. For 1.15, 1.16, 1.17, 1.18, 1.20C, 1.20D, 1.22, and 1.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the pandemic period or post-pandemic evaluation period. For claims determined or decided during the pandemic period or post-pandemic evaluation period, all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

* * * * *

Part B

* * * * *

101.00 Musculoskeletal Disorders.

* * * * *

C. * * *

7. * * *

a. The term *pandemic period* as used in 101.00C7c means the period beginning on April 2, 2021, and ending on May 11, 2025. The term *post-pandemic evaluation period* as used in 101.00C7c means the period beginning on May 12, 2025, and ending on May 11, 2029.

* * * * *

c. For 101.15, 101.16, 101.17, 101.18, 101.20C, 101.20D, 101.22, and 101.23, all of the required criteria must be present simultaneously, or within a close proximity of time, to satisfy the level of severity needed to meet the listing. The phrase ''within a close proximity of time'' means that all of the relevant criteria must appear in the medical record within a consecutive 4-month period, except for claims determined or decided during the pandemic period or post-pandemic evaluation period. For claims determined or decided during the pandemic period or post-pandemic evaluation period, all of the relevant criteria must appear in the medical record within a consecutive 12-month period. When the criterion is imaging, we mean that we could reasonably expect the findings on imaging to have been present at the date of impairment or date of onset. For listings that use the word ''and'' to link the elements of the required criteria, the medical record must establish the simultaneous presence, or presence within a close proximity of time, of all the required medical criteria. Once this level of severity is established, the medical record must also show that this level of severity has continued, or is expected to continue, for a continuous period of at least 12 months.

* * * * *

[FR Doc. 2025–01283 Filed 1–16–25; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 16

[Docket No. FDA–2024–N–3654]

RIN 0910–AI97

Regulatory Hearing Before the Food and Drug Administration; General Provisions; Amendments; Withdrawal

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) published in the **Federal Register** of September 20, 2024, a direct final rule amending the Scope section of our regulation that provides for a regulatory hearing before the Agency. The comment period closed December 4, 2024. FDA is withdrawing the direct final rule because the Agency received significant adverse comment.

DATES: The direct final rule published at September 20, 2024, 89 FR 77019, is withdrawn effective January 17, 2025.

FOR FURTHER INFORMATION CONTACT: Robert Schwartz, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 20, 2024, 89 FR 77019 is withdrawn.

Dated: January 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01145 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2022–C–0098]

Listing of Color Additives Exempt From Certification; Myoglobin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; order.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of myoglobin as a color additive in ground meat and ground poultry analogue products. We are taking this action in response to a color additive petition (CAP) submitted by Motif FoodWorks, Inc. (Motif FoodWorks or petitioner).

DATES: This order is effective February 19, 2025. See section X for further information on the filing of objections. Either electronic or written objections and requests for a hearing on the order must be submitted by February 18, 2025.

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

Please note that late, untimely filed objections will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 18, 2025. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2022–C–0098 for ''Listing of Color Additives Exempt From Certification; Myoglobin.'' 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, 240–402–7500.

- 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 *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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Office of Pre-market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1309 or Keronica Richardson, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1262.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a document published in the **Federal Register** of February 14, 2022 (87 FR 8222), we announced that FDA filed a color additive petition (CAP 2C0322) submitted by Motif FoodWorks, Inc., 27 Drydock Ave., 2nd Floor, Boston, MA 02210. The petition proposed to amend the color additive regulations in part 73 (21 CFR part 73), ''Listing of Color Additives Exempt from Certification'' to provide for the safe use of myoglobin as a color additive in ground meat and ground poultry analogue products where the amount of myoglobin protein does not exceed 2 percent by weight of the uncooked analogue product.

The petition used the terms ''analogue'' and ''alternative'' interchangeably to describe the type of food products in which the color additive is intended for use. This order will use the phrase ''ground meat and ground poultry analogue products,'' which refers to plant-based ground meat- and poultry-like food products, such as patties, sausages, links, and nuggets, subject to FDA regulation. (The petitioned use of this color additive does not include use in cell-cultured meat and poultry products under regulatory authority of the United States Department of Agriculture.)

The petition described myoglobin protein as the characterizing coloring component of a stabilized liquid mixture that imparts a red to pink coloration in uncooked ground meat and ground poultry analogue products to give an appearance similar to raw meat and poultry. The petition referred to the color additive as ''myoglobin'' or ''myoglobin preparation.'' For the purposes of this order, we refer to ''myoglobin preparation'' as the stabilized liquid mixture that contains myoglobin protein and note that ''myoglobin'' and ''myoglobin preparation'' are used interchangeably to refer to this color additive. We are establishing ''myoglobin'' as the common or usual name for this color additive.

II. Background

The color additive that is the subject of this petition is the stabilized product of controlled fermentation of a non-pathogenic and non-toxicogenic strain of the yeast, *Komagataella phaffii* (*K. phaffii*), genetically engineered to express myoglobin protein, the principal coloring component. Although the organism is referred to as *Pichia pastoris* (*P. pastoris*) throughout the petition, we note that the nomenclature for *P. pastoris* was reassigned based on genetic typing to *Komagataella phaffii.* (Ref. 1). We are referring to the organism hereafter as *K. phaffii* to reflect the current taxonomic identity.

The color additive is manufactured by the following steps: (1) construction of the *K. phaffii* production strain that is

genetically engineered to express a synthetic myoglobin gene from *Bos taurus;* (2) expression of myoglobin protein via submerged fed-batch fermentation by the *K. phaffii* production strain; (3) disruption of the *K. phaffii* cells by mechanical shearing to release myoglobin protein and removal of the *K. phaffii* cells by washing, lysing, centrifugation, and microfiltration; (4) ultrafiltration to concentrate the myoglobin protein; and (5) stabilization of the expressed protein as a liquid preparation. The gene that is inserted into the *K. phaffii* is generated by DNA synthesis and is not obtained directly from the DNA of *Bos taurus.* The amino acid sequence of the expressed myoglobin protein is identical to bovine myoglobin protein that has a history of being safely consumed.

Based on information in the petition, the myoglobin preparation has a moisture content of ≥92.5 percent, a myoglobin protein content of ≥3 percent, and may contain stabilizers, preservatives, and antimicrobial agents such as sodium phosphate, sodium ascorbate, and sodium chloride. The color additive is stored as a frozen liquid. FDA concurs with the petitioner that the genetic modifications made to generate the non-toxigenic and non-pathogenic production strain are well-characterized and the production process conforms to good manufacturing practice (Ref. 2). We are requiring a specification for the minimum purity of myoglobin protein as a percent of the total protein in the color additive and a specification limit for lead. The petitioner provided analytical data from the analyses of five lots of myoglobin preparation showing that the color additive can be manufactured to meet these specifications.

We have previously considered the safety of myoglobin preparation based on a submission from Motif FoodWorks, to which we had no questions, that the use of myoglobin preparation to impart flavor and aroma in ground meat and poultry analogue products is generally recognized as safe (GRAS). Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321(s)), a substance is GRAS if it is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food before January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. Under section 201(s) of the FD&C Act, a substance that is GRAS for a particular use in food is not a food additive and may lawfully be utilized for that use without our review and approval. There is no GRAS exemption, however, to the definition of a color additive in section 201(t) of the FD&C Act. Therefore, we must approve the use of a color additive in food before it is marketed; otherwise, the food containing the color additive is adulterated under section 402(c) of the FD&C Act (21 U.S.C. 342(c)).

A firm may voluntarily submit to FDA information supporting the firm's conclusion that a substance is GRAS for its intended use in food through our GRAS Notification Program (see 81 FR 54960, August 17, 2016). Through this program, a GRAS conclusion was submitted by Motif FoodWorks and filed on June 28, 2021, as GRAS Notice 001001(GRN 001001). This GRN informed FDA that Motif FoodWorks concluded that the use of myoglobin preparation at levels providing up to 2 percent myoglobin protein to impart flavor and aroma in ground meat and poultry analogue products was GRAS. Based on our evaluation of the information provided in GRN 001001, as well as other available information, we issued a response letter on December 3, 2021, to Motif FoodWorks stating that we had no questions regarding its conclusion that myoglobin preparation is GRAS for its intended conditions of use. In our response letter to Motif FoodWorks, we stated that because myoglobin preparation imparts a red coloration when exposed to oxygen in some food applications, its use may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA regulations in 21 CFR part 70. The specific use of myoglobin preparation to impart a reddish, meat-like color to ready-to-cook meat and poultry analogue products is important to the appearance and marketability of the analogue products. As such, this use of myoglobin preparation requires premarket approval as a color additive (see § 70.3(g) (21 CFR 70.3(g))).

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 proposed 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) 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 to establish with reasonable certainty that a color additive is not harmful under its intended conditions of use, we consider the additive's manufacturing and stability, the projected human dietary exposure to the additive and any impurities resulting from the petitioned use of the additive, the additive's toxicological data, and other relevant information (such as published literature) available to us.

IV. Safety of Petitioned Use of the Color Additive

A. Dietary Exposure Estimate

Myoglobin preparation is composed mainly of water, myoglobin protein, minor quantities of *K. phaffii* proteins, ash, fat, carbohydrates, and stabilizers and preservatives such as sodium phosphate, sodium ascorbate, and/or sodium chloride. During our safety review of this color additive petition, we evaluated the dietary exposure estimates for the myoglobin preparation, the myoglobin protein component, and selected nutrients of the preparation. The petitioner provided two sets of dietary exposure estimates. For one set of estimates, the petitioner used U.S. food consumption for meat and poultry analogue products (*e.g.,* soy burgers, vegetarian hot dogs) from the combined 2013 to 2018 National Health and Nutrition Examination Survey (NHANES) and assumed these products contained myoglobin preparation at use levels that would result in myoglobin protein concentrations of 1 percent, 1.5 percent, and 2 percent in the food. The petitioner noted that typical use levels of myoglobin protein are expected to be 1 to 1.25 percent for most food categories. The petitioner estimated the eaters-only dietary exposure to myoglobin preparation at the maximum use level of 2 percent myoglobin protein for the U.S. population aged 2 years and older to be 43.7 grams/person/day (g/p/d) at the mean and 97.6 g/p/d at the 90th percentile. For the myoglobin protein, the eaters-only dietary exposure for the U.S. population aged 2 years and older was estimated to be 1.3 g/p/d at the mean and 2.9 g/p/d at the 90th percentile.

The petitioner provided a second set of dietary exposure estimates based on a use level of 1 percent myoglobin protein and food consumption data for conventional ground meat and ground poultry products assuming a 1:1 substitution for ground meat and ground poultry analogue products. For these estimates, the petitioner selected NHANES food codes that represented the most common food applications in which myoglobin preparation is expected to be used (*i.e.,* ground patties,

crumbles, links, bacon, sausage, and meatballs from beef, pork, or poultry). The petitioner estimated the mean and 90th percentile eaters-only dietary exposures to myoglobin protein for the U.S. population aged 2 years and older to be 0.7 g/p/d and 1.5 g/p/d, respectively, and for ages 2 to 5 years to be 0.3 g/p/d and 0.7 g/p/d, respectively.

FDA replicated and confirmed the petitioner's two sets of estimates of dietary exposure to myoglobin protein and myoglobin preparation. We also conducted a third analysis using 2021 *per capita* food availability data for retail beef and poultry in the United States (USDA Economic Research Service), the assumption of a 1:1 substitution with meat and poultry alternative products, and a use level that provides 2 percent myoglobin protein in the food. FDA estimated the dietary exposure to myoglobin protein and myoglobin preparation for U.S. consumers to be 3.9 g/p/d and 129 g/p/d, respectively. We note that dietary exposures based on availability data typically overestimate *per capita* consumption because the data do not consider food loss and wastage (Ref. 2).

The petitioner also estimated dietary exposures to iron from the petitioned use of the color additive using the first two methods described above. Based on NHANES consumption data for ground meat and ground poultry analogue products and the maximum intended use level of 2 percent myoglobin protein, the petitioner estimated the mean and 90th percentile eaters-only dietary exposures to iron for the U.S. population aged 2 years and older to be 2.0 and 4.5 mg/p/d, respectively. Based on a use level of 1 percent myoglobin protein and food consumption data for conventional ground meat and ground poultry products assuming a 1:1 substitution for ground meat and ground poultry analogue products, the petitioner estimated the mean and 90th percentile eaters-only dietary exposures to iron for the U.S. population aged 2 years and older to be 1.0 and 2.0 mg/p/d, respectively, and for ages 2 to 5 years to be 0.5 and 1.0 mg/p/d, respectively.

B. Toxicological Considerations

To establish that myoglobin preparation is safe for use as a color additive that provides up to 2 percent myoglobin protein in ground meat and ground poultry analogue products, the petitioner used a weight-of-evidence approach based on the following: (1) the history of widespread and safe consumption of bovine myoglobin protein; (2) the safety of *K. phaffii* as a production organism; and (3) an allergenicity assessment of myoglobin and *K. phaffii* proteins.

Based on our review of this petition (CAP 2C0322), we conclude that the proteins in the myoglobin preparation are well defined, nontoxic, and not likely to cause an allergenic response when consumed (Ref. 3). Because the myoglobin protein expressed in *K. phaffii* is 100 percent identical in amino acid sequence to bovine myoglobin protein, we conclude that the history of safe consumption of bovine myoglobin protein from ingestion of meat in the diet can be extended to the safety of Motif FoodWorks' myoglobin protein. Regarding the *K. phaffii* strain developed by the petitioner for the production of myoglobin preparation, we conclude that it is non-toxicogenic and non-pathogenic.

We agree that the petitioned uses of the color additive are not expected to increase the dietary exposure to myoglobin protein and iron in the U.S. population, as the consumption of ground meat and poultry analogue products are substitutional for conventional ground meat and poultry products (Ref. 2). Furthermore, we note that the estimated 90th percentile eaters-only dietary exposures to *K. phaffii*-expressed myoglobin protein and iron are well below the Institute of Medicine's recommended dietary reference intakes for protein and iron for all age groups considered (Ref. 3).

In its assessment of the allergenicity of myoglobin preparation, the petitioner examined the incidence of beef allergy in consumers and bioinformatic analyses to determine if the myoglobin and *K. phaffii* proteins found in the myoglobin preparation share significant sequence identity to known allergens. We agree that the weight of evidence demonstrates the safety of myoglobin protein consumption based on the absence of beef allergy case reports since 2004; the lack of the native *Bos taurus* glycosylation pattern in Motif FoodWorks's myoglobin protein, which makes the color additive less likely to trigger an allergic reaction; and a lack of immunologically meaningful sequence identity similarities between the myoglobin preparation proteins and known allergenic proteins. Furthermore, we conclude that myoglobin and *K. phaffii* proteins in the color additive are readily digested at acidic pH conditions found in the stomach and denatured at normal cooking temperatures. Therefore, FDA agrees with the conclusion that myoglobin protein produced in *K. phaffii* is not likely to pose a risk of allergenicity or toxicity upon consumption (Ref. 3).

V. Conclusion

Based on the data and information in the petition and other available relevant information, we conclude that the petitioned use of myoglobin preparation as a color additive in ground meat and ground poultry analogue products is safe, provided the amount of myoglobin protein does not exceed 2 percent by weight of the uncooked product. We further conclude that this color 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 to provide for the safe use of myoglobin, the established common or usual name for this color additive, as set forth in this document. In addition, based on the factors in 21 CFR 71.20(b), we conclude that batch certification of myoglobin is not necessary to protect the public health.

VI. 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 **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15(b), we will delete from the documents any materials that are not available for public disclosure.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

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

IX. Section 301(ll) of the FD&C Act

Our review of this petition was limited to section 721 of the FD&C Act. This order 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 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 color additive. Accordingly, this order should not be construed to be a statement that a food containing this color 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 orders 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.

X. Objections

This order 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 Dockets Management Staff (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.

Any objections received in response to the regulation may be seen in the Dockets Management Staff 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**.

XI. References

The following references are on display at 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.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. Kurtzman C.P., ''Biotechnological Strains of Komagataella (Pichia) Pastoris Are Komagataella Phaffii as Determined From Multigene Sequence Analysis,'' *Journal of Industrial Microbiology and Biotechnology,* 36(11):1435–1438, 2009. Doi: 10.1007/s10295–009–0638–4. PMID: 19760441.
2. Memorandum from J. Mihalov, Chemistry Review Team, Division of Food Ingredients (DFI), Office of Food Additive Safety (OFAS), Center for Food Safety and Applied Nutrition (CFSAN), FDA to E. Anderson, DFI, OFAS, CFSAN, FDA, August 23, 2024.
3. Memorandum from S. Choudhuri, Toxicology Review Team, DFI, OFAS, CFSAN, FDA to E. Anderson, DFI, OFAS, CFSAN, FDA, August 23, 2024.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is 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. Add § 73.297 to subpart A to read as follows:

§ 73.297 Myoglobin.

(a) *Identity.* (1) The color additive myoglobin is a stabilized product of controlled fermentation of a non-pathogenic and non-toxicogenic strain of the yeast, *Komagataella phaffii,* genetically engineered to express the myoglobin protein from *Bos taurus.* Myoglobin protein is the principal coloring component of the color additive and imparts a red color.

(2) Color additive mixtures made with myoglobin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Myoglobin must conform to the following specifications and must be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practice:

(1) Myoglobin protein purity on protein basis (weight/weight), not less than 85 percent.

(2) Lead, not more than 0.01 milligrams per kilogram (0.01 parts per million).

(c) *Uses and restrictions.* Myoglobin may be safely used in ground meat and ground poultry analogue products (*i.e.,* plant-based ground meat- and poultry-like food products subject to FDA regulation) where the amount of myoglobin protein does not exceed 2 percent by weight of the uncooked analogue product.

(d) *Labeling.* The label of the color additive and of any mixture prepared therefrom intended solely or in part for coloring purposes must conform to § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01239 Filed 1–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF STATE

22 CFR Part 121

[Public Notice: 12441]

RIN 1400–AF42

International Traffic in Arms Regulations: U.S. Munitions List Targeted Revisions

AGENCY: Department of State.

ACTION: Interim final rule; request for comments.

SUMMARY: The Department of State (the Department) amends the International Traffic in Arms Regulations (ITAR) to remove from the U.S. Munitions List (USML) items that no longer warrant inclusion, add to the USML items that warrant inclusion, and clarify certain entries. With these amendments, the Department also supersedes and thus terminates the temporary modification to USML Category VIII that was published on December 4, 2023, and extended on November 26, 2024.

DATES:

Effective date: September 15, 2025.

Comment due date: Send comments by March 18, 2025.

ADDRESSES: Interested parties may submit comments to the Department of State by any of the following methods:

- *Visit the Regulations.gov website at: https://www.regulations.gov* and search for the docket number DOS–2024–0047.