DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA–2023–N–0437]

Micro-Tracers, Inc.; Response to Objections and Requests for a Public Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; response to objections and denial of public hearing requests; removal of administrative stay.

SUMMARY: The Food and Drug Administration (FDA or we) received objections and requests for a public hearing submitted by Buchanan Ingersoll & Rooney PC, on behalf of Micro-Tracers, Inc. (Micro-Tracers or objector), on the order granting a color additive petition (3C0323) requesting that we repeal specified regulations to no longer provide for the safe use of FD&C Red No. 3 in food (including dietary supplements) and ingested drugs. After reviewing the objections, we have concluded that the objections do not raise issues of material fact that justify a hearing. We are also providing notice that the administrative stay of the effective date for the repeal and delisting of the color additive regulations is now lifted.

DATES: This order that published in the **Federal Register** of January 16, 2025 (90 FR 4628) with effective dates of January 15, 2027, and January 18, 2028, was administratively stayed by the filing of objections under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)(2)) as of February 18, 2025. FDA lifts the administrative stay as of August 5, 2026. The effective dates of January 15, 2027, and January 18, 2028, for amendatory instruction 4, for the order published on January 16, 2025 (90 FR 4628), are confirmed.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule 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: Shayla West-Barnette, Office of Pre-Market Additive Safety, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1262; or Alexandra Beliveau, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 17, 2023 (88 FR 10245), we announced that we filed a color additive petition (CAP 3C0323) (petition) jointly submitted by the Center for Science in the Public Interest, Breast Cancer Prevention Partners, Center for Environmental Health, et al. (petitioners), which proposed that we repeal the color additive regulations for FD&C Red No. 3 at §§ 74.303 (21 CFR 74.303) and 74.1303 (21 CFR 74.1303) to no longer provide for the safe use of FD&C Red No. 3 in food (including dietary supplements) and ingested drugs, respectively. The petition cited section 721(b)(5)(B) of the FD&C Act (21 U.S.C. 379e(b)(5)(B)), often referred to as the Delaney Clause, which deems color additives unsafe under certain circumstances. The relevant provision, section 721(b)(5)(B)(i) of the FD&C Act, states that a color additive shall be deemed unsafe for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary of Health and Human Services (Secretary) to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal.

In the **Federal Register** of January 16, 2025 (90 FR 4628), we issued an order titled ''Color Additive Petition from Center for Science in the Public Interest, et al.; Request to Revoke Color Additive Listing for Use for FD&C Red No. 3 in Food and Ingested Drugs'' (January 2025 order) amending the color additive regulations at §§ 74.303 and 74.1303 to no longer provide for the safe use of FD&C Red No. 3 in food (effective January 15, 2027) and ingested drugs (effective January 18, 2028), respectively. We determined that information provided in the petition and other publicly available relevant data demonstrated that FD&C Red No. 3 has been shown to cause cancer in male rats, and thus its use as a color additive was deemed unsafe under the Delaney Clause as a matter of law (90 FR 4628 at 4631). We gave interested persons until February 18, 2025, to file objections and requests for a hearing on the order.

II. Objections and Requests for a Hearing

Sections 701(e)(2) and 721(d) of the FD&C Act collectively provide that, within 30 days after publication of an order relating to a color additive regulation, any person adversely affected by such an order may file objections, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. We may deny a hearing request if the objections to the order do not raise genuine and substantial issues of fact that can be resolved at a hearing (§ 12.24(b)(1) (21 CFR 12.24(b)(1))). (See also *Community Nutrition Institute* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985)).

Under our regulations at 21 CFR 71.30, objections and requests for a hearing relating to color additive regulations are governed, in part, by 21 CFR part 12. Under 21 CFR 12.22(a), each objection must: (1) be submitted on or before the 30th day after the date of publication of our decision; (2) be separately numbered; (3) specify with particularity the provision of the regulation or proposed order objected to; (4) specifically state each objection on which a hearing is requested (failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection); and (5) include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested (failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection).

Following the publication of the final order in which we granted the petition to amend the color additive regulations to no longer provide for the safe use of FD&C Red No. 3 in food and ingested drugs, we received one submission from Buchanan, Ingersoll & Rooney PC, on behalf of Micro-Tracers (see submission from Edward John Allera, Of Counsel, Barbara A. Binzak Blumenfeld, Ph.D., Shareholder, Natalie C. Oehlers, Associate, and Natalie Crow, Associate, Buchanan, Ingersoll & Rooney PC (Counsel for Micro-Tracers) submitted to the Dockets Management Staff, Food and Drug Administration, dated February 18, 2025) (submission). The submission states that it raises three specific objections to the order and requests hearings on each of them.

We note that the submission includes a copy of comments from Micro-Tracers on the notice of filing of the petition (submission attachment 2). However, because these comments, dated

November 13, 2023, were submitted after the comment period closed on May 18, 2023 (88 FR 19026, March 30, 2023), they were not included in the docket.

III. Standards for Granting a Hearing

The criteria for granting a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by an objector shows that: (1) there is a genuine and substantial factual issue for resolution at a hearing (a hearing will not be granted on issues of policy or law); (2) the factual issue can be resolved by available and specifically identified reliable evidence (a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions); (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the objector (a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate); (4) resolution of the factual issue in the way sought by the objector is adequate to justify the action requested (a hearing will not be granted on factual issues that are not determinative with respect to the action requested, *e.g.,* if the action would be the same even if the factual issues were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation particularizing statutory standards (the proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved); and (6) the requirements in other applicable regulations, *e.g., 21 CFR 10.20, 12.21, 12.22, 314.200, 514.200,* and *601.7(a),* and in the document issuing the final regulation or the notice of opportunity for a hearing are met.

In general, in an administrative proceeding under section 701(e) of the FD&C Act (21 U.S.C. 371(e)), FDA is authorized to issue a decision without holding a part 12 hearing when a party's objections do not raise a genuine and material issue of fact that, if proved in that party's favor, would suffice to warrant the relief requested (see *Community Nutrition Inst.* v. *Young,* 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied,* 475 U.S. 1123 (1986); see also *Vermont Dep't of Pub. Serv.* v. *FERC,* 817 F.2d 127, 140 (D.C. Cir. 1987)). A party seeking a hearing must meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA,* 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify sufficient factual evidence that would be the subject of a hearing, there is no reason to hold one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law (see *Rule 56, Federal Rules of Civil Procedure*). The same principle applies to administrative proceedings (see § 12.24). In reviewing whether an objecting party made an ''adequate proffer of evidence'' to show that an ''actual dispute exist[s],'' courts consider whether the dispute lies in ''a highly technical area [within] the agency's expertise'' (see *Cerro Wire & Cable Co.* v. *FERC,* 677 F.2d 124, 129 (D.C. Cir. 1982)).

A hearing request must not only contain evidence, but that evidence also must raise a material issue of fact ''concerning which a meaningful hearing might be held'' (*Pineapple Growers Ass'n of Haw.* v. *FDA,* 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, an agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming,* 271 F.2d 281, 286 (8th Cir. 1959), *cert. denied,* 362 U.S. 911 (1960)). A hearing is justified only if the objections are made in good faith and if they raise '''material' issues of fact'' (*Pineapple Growers Ass'n,* 673 F.2d at 1085 (quoting *Pactra Indus., Inc.* v. *CPSC,* 555 F.2d 677, 684 (9th Cir. 1977)). The issues raised in objections ''must be material to the question involved; that is, the legality of the order attached'' (*Pineapple Growers Ass'n,* 673 F.2d at 1085 (quoting *Dyestuffs and Chemicals,* 271 F.2d at 286)). A hearing need not be held to resolve questions of law and policy (see *Kourouma* v. *FERC,* 723 F.3d 274, 278 (D.C. Cir. 2013) (citing *Citizens for Allegan County., Inc.* v. *FPC,* 414 F.2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F.2d 233, 240 (5th Cir. 1958)).

IV. Analysis of Objections and Response to Hearing Requests

The submission contains three numbered objections and requests a hearing on each objection. We address each objection below, as well as the evidence and information filed in support of each, including our evaluation of whether each objection and the information submitted in support of it satisfies the standards for granting a hearing in § 12.24(b).

A. Objection 1

In Objection 1, the objector states that it objects to the ''scientific basis'' for the revocation of these color additive listings and argues that ''FDA erred in its statistical interpretation of the data that formed the basis for FDA's decision to revoke these two regulations'' (submission at page 20). In support of these assertions, the objector provides an opinion titled ''Bayesian Statistical Reanalysis of Red Dye 3 Thyroid Neoplasms'' by Lyle D. Burgoon, Ph.D. (submission attachment 4). For purposes of our discussion of the objector's arguments, we group them under two general categories: (1) FDA's use of the sum of carcinomas and adenomas and (2) FDA's analysis of the data.

First, the objector asserts that FDA should not have used the sum of carcinomas and adenomas when determining that FD&C Red No. 3 caused cancer in male rats. The objector argues that the Delaney Clause does not permit FDA to consider adenomas when determining whether a color additive ''induces cancer.'' The objector asserts ''the Delaney Clause specifically prohibits the use of color additives . . . that will 'induce cancer' when ingested by humans or animals . . . . Carcinomas are malignant (cancerous tumors), but *adenomas* are benign (non-cancerous) tumors. Therefore, it was arguably inappropriate to include the sum of carcinomas *and* adenomas when assessing the historical data'' (submission at page 21 and submission attachment 4 at page 1). The objector also asserts that ''it is well established that thyroid adenomas rarely become carcinomas, especially thyroid follicular adenomas (5 percent of adenomas are reported to be cancers according to StatPearls). Thus, it is wholly inappropriate to sum adenomas and carcinomas, under the assumption that adenomas will become carcinomas'' (submission attachment 4 at page 2).

Second, the objector disagrees with FDA's analysis of the data. The objector asserts that (1) FDA did not consider all of the data together in its statistical analysis, (2) the data was unreliable, and (3) based on his statistical analysis of the data, the ''4-percent group did not actually see an increase in carcinomas once you consider all of the data together, and once you consider the historical background rate of thyroid

carcinomas in the vehicle animals'' (id. at pages 1 through 2).

With respect to FDA's consideration of data in its statistical analysis, the objector asserts: ''FDA takes an antiquated approach (by today's standards) to analyze the cancer data . . . . [R]elying strictly on a p-value for decision making is highly inappropriate . . . . Ronald Fisher, the father of the p-value, has stated in numerous texts that all that a significant p-value means is that additional testing is warranted . . . . A more robust and modern way to analyze this data is to take a more Bayesian approach . . . The advantage of this approach is that we can get a better sense of the background/historical cancer rate in the vehicle control animals'' (id. at page 7). The objector asserts that FDA ''did not consider all of the data together—it still only considers the data separately. Thus, . . . FDA is not considering the fact of regression towards the mean nor is [FDA] considering the impacts of small sample sizes in causing false positive results'' (id. at page 1). The objector also asserts that ''A reasonable scientist considers the total weight of the evidence, not any one, singular study on its own'' (id.).

With respect to the reliability of the data, the objector asserts that the sample sizes of the studies were ''too small to be reliable predictors of the population response'' (submission at page 22). The objector asserts that the ''studies included potentially confounding variables, including differences in mean body weight, food consumption, and thyroid follicular cell hyperplasia'' (id.). The objector further asserts that ''Sprague-Dawley rats have a relatively high background rate of follicular cell adenomas and carcinomas, according to historical control data from LabCorp published in the journal Toxicologic Pathology'' (submission attachment 4 at page 2).

With respect to conclusions made based on the objector's statistical analysis of the data, the objector asserts that ''the 4-percent group is not meaningfully different from the vehicle controls,'' as evidenced by the difference distribution calculation, and FDA should have considered the petitioners' data unreliable due to sample bias and rejected the petition (id. at pages 11 through 12). The objector reiterates the basis for this decision as being three-fold: ''(1) relying upon unreliable data, (2) relying upon data that showed there was too much uncertainty to draw a conclusion (thus, the data were unreliable), and (3) when looking at all of the data together, it is clear that there is no evidence that the 4-percent group caused cancers at a higher rate than the vehicle controls (*i.e.,* FD&C Red No. 3 does not cause cancer at a rate that is biologically meaningfully different from the background rate)'' (id. at page 12). Additionally, the objector asserts that FDA erred when combining instances of adenomas and carcinomas, as ''over 95 percent of adenomas do not become carcinomas'' (id.) The objector also states that Congress, when passing the amendment that included the Delaney Clause, was ''clear and unambiguous'' in its understanding that the definition of ''cancer'' does not include ''benign tumors'' or ''adenomas'' (id.). Therefore, the objector concludes that FDA ''erred and violated the clear direction given by Congress'' in our reading of the Delaney Clause (id.).

Finally, the objector also argues that ''FDA should have convened a Color Additive Advisory Committee, as one comment on the Petition had requested, because there is genuine debate about the science underlying the Final Order'' (submission at page 22).

FDA's Response: We disagree with the objector's assertions that that the scientific basis for our decision was erroneous or that we erred in our statistical interpretation of the data. The objector asserts that there is an ''ongoing controversy regarding whether [FD&C Red No. 3] is a known animal carcinogen'' (submission attachment 4 at page 2). However, FDA's conclusion that FD&C Red No. 3 induces cancer in male rats, and therefore, is subject to the Delaney Clause, has long been agreed upon by scientific experts.

First, we address the objector's arguments regarding our including the sum of carcinomas and adenomas. The objector asserts that the Delaney Clause does not permit FDA to consider adenomas (id. at pages 1 and 7); however, this is an issue of law, and no hearing is warranted to adjudicate it (§ 12.24(b)(1)). Furthermore, the objector asserts that ''it is well-established that thyroid adenomas rarely become carcinomas''; however, the objector fails to support these assertions with supporting studies and only mentions StatPearls without any further citation (id. at page 2). These general and unsupported assertions fail to raise a ''factual issue [that] can be resolved by available and specifically identified reliable evidence'' (21 CFR 12.24(b)(2)).

We also conclude that the objector's arguments about including the sum of carcinomas and adenomas do not provide a basis for amending or revoking our January 2025 order. We discussed the rationale for including the sum of carcinomas and adenomas in male rats administered FD&C Red No. 3 in our denial of CAP 9C0096 (which requested the permanent listing of FD&C Red No. 3 as a color additive for use in cosmetics, including lipsticks and other ingested cosmetics, and externally applied drugs) (55 FR 3520, February 1, 1990). In our denial, which was based on the Delaney Clause, we stated that the petition's ''failure to find a significant tumorigenic effect was apparently because its statistical analysis treated adenomas and carcinomas as separate tumor classes'' (id. at 3525). Specifically, we stated that the petitioners ''apparently distinguished between oncogenicity and carcinogenicity and between the ability of FD&C Red No. 3 to induce adenomas and carcinomas'' (id.). We further explained that the petitioners used this separation of tumors into adenomas and carcinomas as the basis for later testing for statistically significant differences of tumor incidence between treated and control groups. By contrast, we explained that although FDA also separately analyzes the incidences of adenomas and carcinomas, we extend our analysis further by using the combined incidences of adenomas and carcinomas and then statistically comparing the combined incidence of tumors in treated animals with the control groups (id.). We concluded that our ''approach to tumor analysis is appropriate because it is entirely sound to interpret thyroid follicular cell adenomas as an earlier stage in a series of progressive proliferative changes leading to the expression of follicular cell carcinomas'' (id.). We also noted that the National Toxicology Program (NTP) Subcommittee, in conducting its review, also considered the combining of carcinomas and adenomas to be an appropriate procedure (id.). As we describe below, this continues to be NTP's approach.

We disagree with the objector's assertion that ''it is wholly inappropriate to sum adenomas and carcinomas, under the assumption that adenomas will become carcinomas'' (submission attachment 4 at page 2). The Center for Food Safety and Applied Nutrition (now the Human Foods Program (HFP))'s Cancer Assessment Committee (CAC) described the likely mode of action which resulted in the thyroid cancer in male rats that was observed in the Borzelleca et al. study and the weight of evidence for that mode of action (Ref. 1) (2018 CAC Memorandum). The 2018 CAC Memorandum states ''the committee agreed that there were hormonal key events leading to thyroid follicular neoplasia in male rats based on

proliferative changes including dose- and time-dependent thyroid follicular hyperplasia in the lifetime bioassay and hypertrophy in shorter mechanistic studies. The committee also discussed the reported impact of FD&C Red No. 3 on levels of serum thyroid-stimulating hormone (TSH) and other thyroid hormones (T4/T3/rT3), and the well-characterized causal connection between high levels of TSH in the rat and the resulting induction of thyroid follicular cell neoplasia'' (id. at page 8). The 2018 CAC Memorandum further states that ''the rats exhibited a spectrum of lesions characterized as pre-neoplastic (thyroid follicular hyperplasia), benign neoplastic (follicular cell adenoma) and malignant neoplastic (follicular cell carcinoma, more specifically adenocarcinoma)'' (id.). The CAC determined that increased incidences of thyroid follicular hyperplasia and follicular cell neoplasia (measured as combined adenomas and carcinomas) represented a treatment-related increase in incidences of thyroid neoplasia in male rats (id.).

As part of their discussion of the relevance of the rat mechanism of action to thyroid carcinogenesis in other mammals, the CAC requested input from an expert in endocrine disease in laboratory and domestic animals. The 2018 CAC memorandum noted that the expert explained that ''veterinary pathologists agree that rat thyroid carcinogenesis in response to TSH involves a well-characterized proliferative process of the thyroid follicular tissue, starting with hypertrophy (initially diffuse) followed by multifocal hyperplasia which then progresses to adenomas and ultimately with sufficient time and dose (exposure) to carcinomas'' (id. at page 9). The expert ''pointed out that veterinary pathologists consider TSH an indirect carcinogen and a promoter of neoplasia in the male rat and that as little as a two-fold chronic increase in TSH is sufficient to initiate this proliferative process in this species/sex'' (id.). The expert also stated that ''even if carcinomas are not observed in a particular study, elevated TSH will likely lead to thyroid neoplasia (adenomas and carcinomas) over time in male rats'' (id. at page 10).

The NTP's website titled ''Cancer Evaluation Criteria'' discusses considerations for evaluating evidence of carcinogenic activity (Ref. 2). The NTP states that considerations of carcinogenicity data should consider that ''some benign neoplasms have the capacity to regress but others (of the same morphologic type) progress. At present, it is impossible to identify the difference. Therefore, where progression is known to be a possibility, the most prudent course is to assume that benign neoplasms of those types have the potential to become malignant'' (id.). The NTP also states that the consideration of carcinogenicity data should include ''combining benign and malignant tumor incidences known or thought to represent stages of progression in the same organ or tissue'' (id.). A guide published in 2024 by a Working Group of biopharmaceutical experts from international societies of toxicologic pathology (Society of Toxicologic Pathology, British Society of Toxicologic Pathology, European Society of Toxicologic Pathology, FDA, the International Harmonization of Nomenclature and Diagnostic Criteria initiative, and members of the Standard for Exchange of Nonclinical Data initiative) was published to assist pharmacology/toxicology reviewers and biostatisticians in statistical analysis of nonclinical tumor data (Ref. 3). The guide outlines the approach to determining appropriate combinations of tumors for analysis and lists the following recommendations: ''A. Combine benign tumors of the same cell type by site for analysis. B. Combine malignant tumors of the same cell type by site for analysis. C. Combine benign and malignant tumors of the same cell type by site for analysis'' (id.).

Additionally, FDA conducted further analyses, which note that the probability of adenomas progressing into carcinomas ''depends on several factors, such as aging, changes in chromosomal stability and altered metabolism'' (Ref. 4). We also found that the scientific literature reports that 20 percent of nonfunctioning follicular cell adenomas (with oncogene mutations) can progress into a carcinoma (id.). This indicates that there is a possibility of adenomas becoming malignant (*i.e.,* carcinoma), and the probability of this progression may vary depending on the organ-type, underlying mechanisms, and other factors, as stated elsewhere in this document. In the absence of information on such specific factors, it is not possible to estimate the exact percentage of the chance of progression of adenomas to carcinomas in a particular organ-type or study (id.).

The approach of combining adenomas and carcinomas has also been used by the NTP to evaluate the potential for carcinogenicity of substances. The NTP considers a dose-related increase in either malignant or benign neoplasms, or the combination of malignant and benign tumors for an organ, appropriate to determine if there is evidence of carcinogenic activity of the test substance in the conditions of the reviewed study (id.). Thus, FDA considers using the combined incidences of adenomas and carcinomas as a well-established and conservative approach to cancer risk assessment.

Second, we address the objector's arguments regarding our analysis of the data. The objector argues that the rat carcinogenicity bioassays were insufficiently designed, stating that ''sample sizes in the studies cited are too small to be reliable predictors of the population response'' and ''rat feeding studies include potentially confounding variables, including differences in mean body weight, food consumption, and thyroid follicular cell hyperplasia'' (submission at page 22). In our denial of CAP 9C0096, we discussed our determination that the rat feeding study design was appropriate (55 FR 3520). We stated ''[t]he experimental design for the [International Research Development Corporation (IRDC)] studies of FD&C Red No. 3 benefited from knowledge of the protocol deficiencies in previously conducted carcinogenesis bioassays and other chronic toxicity testing. Improvements in study design included: (1) The use of large numbers of animals of both sexes . . . (3) two control groups (thereby effectively doubling the number of controls) . . . . All of these protocol changes significantly increased the power of these tests to detect dose-related effects. For this reason, FDA believes that the results of the IRDC chronic feeding studies constitute a reliable basis for assessing the safety of FD&C Red No. 3'' (id. at 3524).

Furthermore, the CAC stated that the FD&C Red No. 3 rat carcinogenicity study was appropriately designed and that the CAC determined in 1982–1989 that thyroid neoplasia (tumors) was induced in male rats (Ref. 1). The rat study ''is still appropriate per current guidelines (Redbook 2000, Chapters II.C.5.a. and IV.C.7. or IV.C.8.) and CAC continues to consider it a positive rodent bioassay for mode of action . . . or risk assessment evaluations'' (id.). The CAC previously reviewed the data and information on FD&C Red No. 3 in 1984, 1985, and 1989, and the available data and information were also reviewed by a panel convened by the NTP in 1983 and by an FDA peer review panel in 1987 (Ref. 1). These reviews all reached the conclusion that the dietary administration of FD&C Red No. 3 at high doses (4 percent) was associated with an increase in the incidence of thyroid follicular cell neoplasia in male rats (id.). Furthermore, as discussed in the toxicology memorandum supporting

the January 2025 order, a 1989 European Commission's Scientific Committee for Food report and Joint FAO/WHO Expert Committee on Food Additives also concluded that FD&C Red No. 3 causes cancer in male rats (Ref. 5).

We disagree with the objector's assertion that ''FDA did not consider all of the data together, instead only considering the data separately'' (submission at page 22). Regarding the total weight of evidence for the statistical analysis and statistical power of the carcinogenicity study, FDA reaffirms that ''the study design and protocol for the study were in compliance with FDA's Redbook and OECD Test Guideline 451 for carcinogenicity studies . . . to ensure that sufficient statistical power was achieved'' (Ref. 4). We further note that reliance on the derived p-value to support statistical significance is generally supportive of causation per OECD Test Guidance 116 (id.). In addition to the statistical analysis, FDA pathologists independently examined microslides derived from thyroid tissues of male rats from this study and confirmed a treatment-related increase in thyroid follicular cell neoplasia in the male rats (id.). Thus, FDA's assessment demonstrates a consideration of ''the totality of the available information on the study and utilized an approach based on statistical analysis as well as pathological examination to conclude FD&C Red No. 3 caused thyroid tumors in male rats under the conditions of the study'' (id.).

We disagree with the objector's assertion that ''male rats fed FD&C Red No. 3 at 4 percent of their feed did not see an increase in carcinomas when considering all data together and the historical background rate of thyroid carcinomas in vehicle animals'' (submission at page 22). In our denial of CAP 9C0096, we stated our review found 14/68 or 20.6 percent follicular cell adenomas in the 4-percent group compared with 1/68 or 1.5 percent in the controls (55 FR 3520 at 3524). In addition, our review found carcinomas in 5/68 or 7.4 percent of the 4-percent group compared with 1/68 or 1.5 percent of the controls (id.). FDA's analysis of the incidence of combined adenomas and carcinomas demonstrated a statistically significant increase ($p < 0.0007$ in such tumors: 18/68 (26.5 percent) in the 4-percent group compared with 2/68 (2.9 percent) in controls (id. at 3524 through 3525). Based on our evaluation of the data from the IRDC studies, we concluded that FD&C Red No. 3 causes cancer in male rats (id. at 3525). We note that data provided on the ''high background rate of follicular cell adenomas'' from LabCorp, published in the journal Toxicologic Pathology, report lifetime background instances of thyroid follicular cell adenomas to be 2.8 percent in males and 0.7 percent in females, and thyroid follicular cell carcinomas to be 0.9 percent in males and 0.7 percent in females. Therefore, these historical data generated from over 3,600 rats support our evaluation that a 26.5 percent combined incidence of thyroid follicular cell adenomas and carcinomas, as observed in the 4-percent group, is substantially higher than the background instance rate of 2.8 percent and is thus likely a toxicologically relevant observation.

Furthermore, in the 2018 CAC Memorandum, we addressed the previous findings of the CAC and a panel of the NTP. The CAC reviewed the submitted data and information on FD&C Red No. 3 in 1984, 1985, and 1989, and the available data and information were also reviewed by a panel convened by the NTP in 1983 and by an FDA peer review panel in 1987. These reviews all reached similar conclusions. The dietary administration of FD&C Red No. 3 at high doses (4 percent) was associated with an increase in the incidence of thyroid follicular cell neoplasia in male rats (Ref. 1). Our conclusion on the results of the rat feeding study has not changed, as discussed in the January 2025 order and supporting toxicology memorandum (90 FR 4628 and Ref. 2).

We disagree with the objector's assertion that a Bayesian statistical approach should have been taken when analyzing the data versus a non-Bayesian approach (Ref. 4). We note that Bayesian statistics have the advantage of incorporating the prior distribution or prior knowledge to strengthen the analyses, but the choice of the prior information can influence the results and be seen as introducing bias. In contrast, ''non-Bayesian statistics (*i.e.,* frequentist) are driven by the collected data only and are not affected by the subjectivity from prior distribution or knowledge. Further, non-Bayesian statistics have well-established protocols and interpretation frameworks, as a result of which, such frequentist statistics are applied for scientific research if the sample size (*i.e.,* number of animals per group in a study) is adequate'' (id.). Thus, frequentist statistics are applied for analyzing data from studies with an adequate sample size. In the carcinogenicity study of FD&C Red No. 3, the sample size was adequate for FDA to appropriately use such statistical method of data analysis in our conclusion that FD&C Red No. 3 induced thyroid tumors in male rats under the conditions of the study (id.).

Third, regarding FDA's denial of a request to refer this matter to a color additive advisory committee, neither section 701(e) of the FD&C Act nor our regulations provide for the opportunity to submit objections or request a hearing on such a denial. Section 721(b)(5)(C)(i) of the FD&C Act provides for the referral to an advisory committee for a matter arising under the Delaney Clause that requires the exercise of scientific judgement (see also 21 CFR 14.140). We received one comment in response to the notice of filing of the color additive petition requesting that we refer this matter to a color additive advisory committee. In the January 2025 order, we explained that we declined to convene a color additive advisory meeting because there is not a genuine scientific debate on whether FD&C Red No. 3 induces cancer in male rats, and therefore, the proposal did not require the exercise of scientific judgment (90 FR 4628 at 4632). Because FDA's denial of this request is not the proper subject of objections or a request for a hearing under section 701(e) or section 721(b)(5)(C)(i) of the FD&C Act, the objector's arguments do not provide a basis for us to grant a hearing or to modify or revoke our January 2025 order.

B. Objection 2

In Objection 2, the objector argues that FDA failed to consider: (1) the safety of the specific use of FD&C Red No. 3 in color-coded tracers (submission at page 22); and (2) ''additional legal uses of FD&C Red No. 3 under the general safety provisions of the [FD&C] Act, outside the scope of the Delaney Clause'' (id. at page 20). The objector also references the provision in the Delaney Clause that exempts the use of a color additive as an ingredient in feed for animals which are raised for food production if the Secretary finds that such additive will not adversely affect the animals for which the feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations) in any edible portions of such animals after slaughter or in any food yielded by or derived from the living animal (section 721(b)(5)(B) of the FD&C Act). However, the objector does not assert that this provision, often referred to as the Diethylstilbestrol (DES) Proviso, applies to the intended use of FD&C Red No. 3 in color-coded tracers.

First, the objector asserts that ''these color-coded tracers can be safely used in

food-producing animals'' (id. at page 22). The objector asserts that ''considering the use levels of FD&C Red No. 3 on color-coded tracers . . . the amount of color expected in edible animal tissue, and the human intake of the color, the amounts are vanishingly small'' (id. at page 23). The objector provides estimates on the residues that remain in animal feed and animal tissue (submission attachment 3 at page 2). Therefore, the objector asserts, these amounts can be considered safe under the general safety provisions of the FD&C Act based on the expert statements (submission at page 23).

Second, the objector argues that the Delaney Clause does not apply to FD&C Red No. 3 because ''[w]hen [it] is intended to be used on a color-coded tracer as an analytical tool . . ., it is not a food additive or a color additive; instead, it is subject to the general safety provisions of the [FD&C] Act including [21 U.S.C. 336, 342, 351, and 360b]'' (id. at page 15). Specifically, the objector cites 21 CFR 70.3(g), which provides that a material otherwise meeting the statutory definition of a color additive under section 201(t) of the FD&C Act (21 U.S.C. 321(t)) can be exempt from section 721 of the FD&C Act if it is used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned (id. at pages 16 through 17). The objector argues that colors used as tracers are not used to change food color and do not make the food more appealing for purchase or animal consumption, and that there is no impact on the value or marketability of the medicated article or feed (id. at page 17). Therefore, the objector argues that this use of FD&C Red No 3 is not a color additive use and is not subject to the Delaney Clause (id.).

The objector further argues that the intended use of FD&C Red No. 3 in a color-coded tracer is not a food additive use because it is not intended to become a component of food or to affect the characteristics of the food (id. at pages 17 through 18). The objection argues that color used on a tracer ''is acceptable under [sections 309 and 406 of the FD&C Act] as an unavoidable component'' (id. at page 18). The objector argues that these are ''fact-specific issues'' that require a hearing (id. at page 19).

FDA's Response: With regard to the objector's first argument regarding the safety of the use of FD&C Red No. 3 in tracers, we reiterate that our revocation of the authorization of FD&C Red No. 3 was based on a finding under the Delaney Clause that FD&C Red No. 3 can induce cancer in male rats (90 FR 4628 at 4631). It was not based on a finding that the intended uses are no longer safe under the general safety clause for color additives (see section 721(b)(2)(A) of the FD&C Act; see also 21 CFR 70.3(i): ''safe means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive''). FDA does not have discretion to list a color additive determined to be safe under the general safety clause if it is found to induce cancer under the Delaney Clause. The Delaney Clause clearly states that such color additive ''shall be deemed unsafe, and shall not be listed'' (see section 721(b)(5)(B) of the FD&C Act). Therefore, the objector's argument does not demonstrate how the outcome of this proceeding would be different if its assertions regarding the safety of this intended use were shown to be correct. Courts have recognized the issues raised in objections ''must be material to the question involved; that is, the legality of the order attached'' (*Pineapple Growers Ass'n of Haw.,* 673 F.2d at 1085). Therefore, we are denying the objector's request for a hearing because the factual issues are not determinative with respect to the action requested (21 CFR 12.24(b)(4)), and we conclude that the objector has not provided a basis to modify or revoke the January 2025 order.

With regard to the objector's arguments that the intended use of FD&C Red No. 3 in a tracer is not subject to regulation as a color additive, these arguments are not relevant to the revocation of the listing of FD&C Red No. 3 because the revocation does not change the regulatory status of non-color additive uses. Therefore, these arguments are not within the proper scope of an objection and request for a hearing under section 701(e) of the FD&C Act and do not provide a basis for us to grant a hearing or to modify or revoke the January 2025 order.

Nonetheless, because the objector's assertions misconstrue the definition of a color additive, we briefly address these assertions here to avoid future confusion on this point. Based on its intended use in tracers (Microtracers F), FD&C Red No. 3 is regulated as a color additive because the synthetic dye is added to iron particles used in medicated premixes for purposes of imparting color during a quality assurance testing phase (see 21 U.S.C. 321(t)(1); 21 CFR 70.3(f) through (g)). Specifically, the colored iron particles are isolated from medicated feed samples using a mason jar with a magnetic lid that attracts the colored iron particles (Ref. 6). The colored particles are then sprayed with a water/alcohol mixture. After spraying, the color of the microtracer is clearly visible, which confirms the presence of a specific medicated premix in a finished feed (Refs. 7 and 8). Microtracer F-Red uses FD&C Red No. 3 in medicated premixes containing the new animal drug Skycis (narasin) manufactured by Elanco (submission attachment 3 at page 6). Microtracer FS-Red/Natural Yellow uses FD&C Red No. 3 in combination with Natural Yellow for medicated premixes containing Rumensin (monensin), which is also manufactured by Elanco (id.). Micro-Tracers works with animal drug manufacturers such as Elanco to formulate microtracers that identify their products as proprietary (Ref. 9). This use allows consumers to confirm, based on the color visible during the testing phase, that a medicated feed contains Elanco's proprietary drug instead of generic or no drug at all. Therefore, the use of the color is important with respect to the value, marketability, and consumer acceptability of the medicated feed and is not exempt from the definition of ''color additive'' (21 CFR 70.3(g)). Furthermore, we note that even if the intended use of FD&C Red No. 3 were not regulated as a color additive, it would be regulated as a food additive, which is also subject to the Delaney Clause under section 409(c)(3) of the FD&C Act. Because FD&C Red No. 3 is intentionally added to the tracer, it would not be considered an ''unavoidable component.''

C. Objection 3

In Objection 3, the objector argues that FDA should have either exempted the use of FD&C Red No. 3 in tracers from the revocation of § 74.303 and 74.1303 or should have allowed its use in tracers through the establishment of a safe tolerance level and proposes specific regulatory language (submission at page 21 and submission attachment 7). The objector asserts that FDA ''has not considered the impact of the revocation of these regulations on the use of color-coded tracers intended for use as analytical tools at safe levels of use in medicated articles and medicated feed, nor has it exempted or proposed a safe tolerance level for its continued use for this specific purpose'' (submission at page 21).

FDA's Response: The objector's arguments fail to raise a genuine and substantial issue of fact, and therefore, they do not warrant a hearing (21 CFR 12.24(b)(1)). Nor do the objector's arguments provide a basis for FDA to

modify or revoke the January 2025 order. The only exemption provided for under the Delaney Clause is the DES Proviso. As noted in the discussion of Objection 2, although the objector references the DES Proviso (submission at page 10), the objector has not taken the steps under FDA's regulations to obtain this exemption. The DES Proviso requires a method of examination, as prescribed or approved by regulation, to show that no residue of a color additive will be found in food derived from animals that consume feed containing that color additive (section 721(b)(5)(B) of the FD&C Act). This method of examination is known as a ''regulatory method.'' FDA has codified the steps a sponsor of a compound must follow to establish a regulatory method in 21 CFR part 500, subpart E. Notably, the sponsor is responsible for submitting a proposed method and providing data to show that the method satisfies FDA's operational definition of ''no residue'' (see 21 CFR 500.88). There is no approved regulatory method for FD&C Red No. 3, and the objector does not assert that the necessary data exist to establish a method that complies with the requirements of section 721(b)(5)(B) of the FD&C Act and 21 CFR part 500, subpart E. Without this information, there is no genuine and substantial issue of fact for resolution at a hearing regarding the potential applicability of the DES Proviso to FD&C Red No. 3 as used in color-coded tracers in medicated animal feed (see 21 CFR 12.24(b)(1)).

The DES Proviso cannot exempt the use of FD&C Red No. 3 on tracers used in animal feed unless a proponent demonstrates to FDA that such use will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal under an approved regulatory method (see section 721(b)(5)(B) of the FD&C Act). A proponent must provide the required data to FDA to establish a regulatory method (21 CFR 500.88). Because there is no approved regulatory method, the DES Proviso does not exempt the use of FD&C Red No. 3 in color-coded tracers in animal feed from the Delaney Clause.

Although the objector states that FDA could set a tolerance for the use of FD&C Red No. 3 in color-coded tracers in animal feed, the term ''tolerance'' is legally incompatible with the requirements of the DES Proviso. ''Tolerance'' refers to the maximum concentration of a marker residue, or other residue indicated for monitoring, that can legally remain in a specific edible tissue of a treated animal (21 CFR 556.3). Under the DES Proviso, there must be ''no residue'' of a carcinogenic color additive found in edible tissue or food yielded from the treated animal. In other words, the approved regulatory method cannot find any level of the carcinogenic color additive.

Furthermore, establishing a tolerance limitation for a color additive requires that the proposed use of the color additive be deemed safe (section 721(b)(7) of the FD&C Act). However, as discussed elsewhere in this document, a color additive must be deemed unsafe if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal (section 721(b)(5)(B) of the FD&C Act). Because FD&C Red No. 3 has been found to induce tumors in male rats, it is deemed unsafe as a color additive under the Delaney Clause. As such, the Secretary cannot establish a tolerance limitation for FD&C Red No. 3.

V. Summary and Conclusions

After evaluating the objections, we conclude that the submission does not provide a basis to support modifying or revoking the denial of CAP 3C0323. Therefore, we are overruling the objections and denying the requests for a public hearing.

Under sections 701(e)(2) and 721(d) of the FD&C Act, the filing of objections operates to stay automatically the effectiveness of our repeal of §§ 74.303 and 74.1303 until we take final action on the objections. We have completed our evaluation of the objections and conclude that a continuation of the administrative stay of the effective dates for the repeal of §§ 74.303 and 74.1303 is not warranted.

In the absence of any other objections and requests for a hearing, we conclude that this document constitutes final action on the objections received in response to the January 2025 order as prescribed in section 701(e)(2) of the FD&C Act. Under § 12.28, we are providing notice of our denial and confirming the effective dates of the January 2025 order. Therefore, we are ending the administrative stay of the January 2025 order, and under the January 2025 order we are repealing the listing for FD&C Red No. 3 in § 74.303 as a color additive in food and § 74.1303 as a color additive in ingested drugs effective January 15, 2027, and January 18, 2028, respectively. FDA is repealing these authorizations in a manner consistent with its international obligations. This decision is consistent with the United States' long-standing Appropriate Level of Protection regarding carcinogenic additives in food, which seeks to eliminate exposure to additives that have been found to induce cancer in man or animals.

VI. References

The following references marked with an asterisk (*) 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 also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov,* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

* 1. Center for Food Safety and Applied Nutrition CAC Full Committee Review, Memorandum of Meeting, October 15, 2019.

* 2. National Institutes of Health, National Toxicology Program. ''Cancer Evaluation Criteria.'' *NIH.gov.* Accessed February 2, 2026. Available at *https://ntp.niehs.nih.gov/whatwestudy/testpgm/cartox/criteria.*

3. Keenan, C., M. Al-Haddawi, J.G. Bienvenu, et al. ''Guide for Combining Primary Tumors for Statistical Analysis in Rodent Carcinogenicity Studies.'' *Toxicologic Pathology,* 52(1):13–20, 2024. Accessed February 2, 2026. Available at *https://doi.org/10.1177/01926233241230553.*

* 4. Memorandum from T. Cheng, Division of Food Contact Substances, Toxicology Review Branch, to J. Gingrich, Division of Food Ingredients, Toxicology Review Branch, May 1, 2026.

* 5. Memorandum from J. Gingrich, Division of Food Ingredients, Toxicology Review Branch, to S. West-Barnette, Division of Food Ingredients, Regulatory Review Branch, June 18, 2024.

6. Micro-Tracers, Inc. ''Quality Assurance with Microtracer F.'' July 2013. Accessed February 2, 2026. Available at *https://microtracers.com/wp-content/uploads/2020/04/A-1-Quality-Assurance-with-Microtracer-F-6-12-13-ZE-1.pdf.*

7. Micro-Tracers, Inc. ''Micro-Tracers Mason Jar Procedure.'' July 2022. Accessed February 2, 2026. Available at *https://www.youtube.com/watch?v=pJ2anNgrdyk.*

8. Huvepharma. ''Microtracer Colour Card.'' 2019. Accessed February 2, 2026. Available at *https://microtracers.com/wp-content/uploads/2019/10/huvepharma_color_card_3c-1.pdf.*

9. Micro-Tracers, Inc. ''Our Story.'' 2025. Accessed September 30, 2025. Available at *https://microtracers.com.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15920 Filed 8–4–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2026–0940]

Safety Zones; Recurring Safety Zones in Captain of the Port Northern Great Lakes

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce various safety zones for maritime events in the Captain of the Port Northern Great Lakes zone. Enforcement of these safety zones is necessary to protect the safety of life and property on the navigable waters immediately prior to, during, and immediately after the events. During the periods in question, the Coast Guard will enforce restrictions upon, and control movement of, vessels in a specified area immediately prior to, during, and immediately after events. During each enforcement period, vessels must stay out of the established safety zone and may only enter with permission from the designated representative of the Captain of the Port Northern Great Lakes.

DATES: The regulations in 33 CFR 165.918 will be enforced for the safety zones identified in the **SUPPLEMENTARY INFORMATION** section below for the dates and times specified.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, contact LT Rebecca Simpson, Sector Northern Great Lakes Waterways Management Division, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the following annual safety zones in the Captain of the Port Northern Great Lakes zone listed in the Table to 33 CFR 165.918:

(a) *Event No. (20):* Elk Rapids Harbor Days Fireworks (Elk Rapids, MI) from 10:00 p.m. through 10:30 p.m. on August 8, 2026.

(b) *Event No. (21):* Nautical City Fireworks (Rogers City, MI) from 10:00 p.m. through 10:30 p.m. on August 16, 2026. In the event of inclement weather, this event will be held on August 23, 2026.

In addition to this notice of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the COTP Northern Great Lakes determines that the safety zones need not be enforced for the full duration stated in this notice, he or she may suspend such enforcement and notify the public of the suspension via Broadcast Notice to Mariners and grant general permission to enter the safety zones.

D.M. Parker,

Commander, U.S. Coast Guard, Acting Captain of the Port Northern Great Lakes.

[FR Doc. 2026–15855 Filed 8–4–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 1206013412–2517–02]

RTID 0648–XF942

Fisheries of the Caribbean, Gulf of America, and South Atlantic; Reef Fish Fishery in the Gulf of America; 2026 Commercial Closure for Greater Amberjack

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is closing the 2026 commercial fishing season for greater amberjack in the Gulf of America (Gulf). Federal regulations require NMFS to close commercial harvest for greater amberjack if landings reach the commercial annual catch target (ACT) during the fishing year, which NMFS has projected will occur by August 5, 2026. The commercial closure for greater amberjack will remain closed through the rest of 2026. This action is necessary to protect the greater amberjack resource in the Gulf.

DATES: The commercial closure is effective from August 8, 2026, through December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, at 727–824–5305 or *kelli.odonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS manages the reef fish fishery and greater amberjack in Gulf Federal waters under the Fishery Management Plan for the Reef Fish Resources of the Gulf (FMP). NMFS and the Gulf Fishery Management Council prepared the FMP, which was approved by the Secretary of Commerce and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

All weights discussed in this temporary rule are in round weight. The metric conversion for the imperial measurement used in this document is 1 pound (lb) equals approximately 0.45 kilograms.

For Gulf greater amberjack, the commercial annual catch limit (ACL) and commercial ACT (the latter of which is equivalent to the commercial quota) are 101,000 lb and 93,930 lb, respectively (50 CFR 622.41(a)(1)(iii) and 622.39(a)(1)(v)). On February 5, 2026, NMFS reduced the commercial harvest levels for Gulf greater amberjack, in accordance with the current accountability measure at 50 CFR 622.41(a)(1)(ii), because commercial landings in 2025 exceeded the commercial ACL (91 FR 5243). During the rest of 2026 fishing year, which ends on December 31, the commercial ACL is 92,816 lb and the commercial ACT is 85,746 lb.

Under 50 CFR 622.41(a)(1)(i), NMFS is required to close the greater amberjack commercial sector if NMFS estimates that commercial landings will reach the commercial ACT during the fishing year. NMFS has projected that the reduced 2026 commercial ACT of 85,746 lb will be reached by August 5, 2026. Accordingly, NMFS closes the commercial harvest of greater amberjack from the Gulf Federal waters from August 8, 2026, through December 31, 2026.

During the commercial closure, the sale or purchase of greater amberjack taken from Gulf Federal waters is prohibited. The prohibition on sale or purchase does not apply to the sale or purchase of greater amberjack that were harvested, landed ashore, and sold prior to the effectiveness of this temporary rule and were held in cold storage by a dealer or processor. The commercial harvest of greater amberjack will re-open on January 1, 2027, the beginning of the following commercial fishing season.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens