Country	Listed person and address	**Federal Register** citation
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	Navio Shipping LLC, Suite 3801, Aspin Commercial Tower Sheikh Zayed Road, PO Box 122471 Dubai, UAE.	89 FR [INSERT **FEDERAL REGISTER** PAGE NUMBER] 7/3/2024.
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Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2024–14642 Filed 7–2–24; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 180

[Docket No. FDA–2023–N–0937]

RIN 0910–AI81

Revocation of Authorization for Use of Brominated Vegetable Oil in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending our regulations to revoke the authorization for the use of brominated vegetable oil (BVO) in food. This action is being taken because there is no longer a reasonable certainty of no harm from the continued use of BVO in food. Specifically, the final rule revokes the authorization for the use of BVO as a food ingredient intended to stabilize flavoring oils in fruit-flavored beverages. There are no authorizations for other uses of BVO in food.

DATES: The rule is effective August 2, 2024. For the applicable compliance date, see section VII ''Effective/Compliance Dates'' in the **SUPPLEMENTARY INFORMATION** section of this document.

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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jason Downey, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–9241; or Philip L. Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

The final rule amends our regulations to revoke the authorization for the only authorized use of BVO in food. We are taking this action because there is no longer a basis to conclude that this use is safe.

BVO is a complex mixture of plant-derived triglycerides that have been reacted to contain atoms of the element bromine bonded to the molecules. BVO has historically been prepared from a variety of vegetable oils, including corn, cottonseed, and olive. More recently, BVO is often prepared from soybean oil and declared on food labels as ''brominated soybean oil.'' BVO is used primarily to help emulsify citrus-flavored soft drinks, preventing them from separating during distribution.

B. Summary of the Major Provisions of the Final Rule

The final rule revokes the only authorization for the use of BVO as an ingredient in food. Specifically, the final rule removes 21 CFR 180.30, ''Brominated vegetable oil.''

C. Legal Authority

We are issuing this final rule consistent with our authority under sections 409(i) and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(i) and 371(a)). We discuss our legal authority in greater detail in section IV of this rule.

D. Costs and Benefits

The costs of this final rule come from reformulating products currently manufactured with BVO, relabeling products currently manufactured with BVO, ingredient substitutes for BVO, and possible changes to sensory product properties (which could lead to decreased consumption). The benefits of this final rule come in the form of public health gains from reduced exposure to BVO. The annualized costs of this rule (with a discount rate of 2 percent), minus the costs of the baseline of gradual voluntary reduction, are $0.02 million to $0.06 million. The first-year costs of the final rule are $6.6 million to $16.6 million. We estimate the annualized reduction in BVO exposure under the final rule relative to the baseline of gradual voluntary reduction to be roughly 0.02 million ounces (oz).

Abbreviation/ Acronym	What it means
BVO	Brominated vegetable oil.
CFR	Code of Federal Regulations.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
GRAS	Generally Recognized as Safe.
NCTR	National Center for Toxicological Research.
ppm	parts per million.

III. Background

A. Need for the Regulation/History of This Rulemaking

BVO has been used as a flavoring oil stabilizer and emulsifier since the 1920s and was listed as generally recognized as safe (GRAS) for this use by FDA. In 1970, FDA concluded that BVO could no longer be regarded as GRAS for use in food because of toxicity concerns under the conditions of use at the time, at a level of approximately 150 parts per million (ppm) in beverages (Ref. 1). FDA removed BVO from the list of ''Substances generally recognized as safe'' in 21 CFR part 121 (now codified under 21 CFR part 182) (35 FR 1049, January 27, 1970). In response, the Flavor and Extract Manufacturers Association submitted a food additive petition requesting FDA approval for use of BVO as a food additive in beverages at a maximum use level of 15 ppm. We reviewed the petition, including results from unpublished BVO studies, and while the available information did not indicate an immediate threat to health from the use of BVO in beverages at 15 ppm, we concluded in our petition response that additional long-term studies were needed to support the 15 ppm limit (Ref. 2).

Based on the data available at the time and the history of use of BVO in food without apparent harm, we determined, in October 1970, that there would be an adequate margin of safety from the use of BVO in beverages at the reduced use level of 15 ppm on an interim basis while additional, longer term safety studies with BVO were conducted (Ref. 1). We established an interim food additive regulation under 21 CFR 121.1234 (later codified at § 180.30 (21 CFR 180.30)) authorizing the use of BVO as a stabilizer for flavoring oils used in fruit-flavored beverages in an amount not to exceed 15 ppm in the finished beverage. We initially authorized this use of BVO on a 3-year interim basis pending the receipt of additional data (35 FR 12062, July 28, 1970), and then for an indefinite period to allow for completion of subsequent safety studies (39 FR 36113, October 8, 1974). BVO is not approved for any other use in food in the United States. BVO is not permitted for use in beverages in some jurisdictions, including Australia, the European Union, Japan, and New Zealand. Some BVO-containing products have been reformulated to replace BVO to market the products in jurisdictions that do not permit the use of BVO in those products, and safe and authorized substitutes for BVO are available and have long been in use for the same functions as BVO.

In 2014, as part of our work to reevaluate food and color additives, we reviewed all available data and information that were relevant to the safety of BVO used as a food ingredient. We also reviewed the memoranda and safety studies in our files regarding BVO and considered current scientific principles and study design practices. We determined that the safety data and information available did not provide evidence of a health threat resulting from the limited permitted use of BVO as a flavoring stabilizer in fruit-flavored beverages, but many studies that we reviewed did not clearly establish safe levels of chronic use (Ref. 3). We identified deficiencies in the existing studies, including poor study design by modern standards, equivocal results, inconsistencies in measured parameters between studies, and suboptimal dose selection (Ref. 3). We concluded that high-quality data from contemporary studies, performed under current guideline standards, were needed to address the knowledge gaps regarding the safety of BVO (Ref. 3).

Therefore, through a collaboration between FDA's Center for Food Safety and Applied Nutrition, the National Center for Toxicological Research (NCTR), and the National Institute of Environmental Health Sciences' Division of Translational Toxicology (formerly the Division of the National Toxicology Program), new rodent safety studies on BVO were designed and executed with the goal of addressing the potential for thyroid toxicity and bioaccumulation.

The rodent safety studies conducted by NCTR were published in 2022 (Ref. 4) and confirmed previous reports that dietary exposure to BVO is toxic to the thyroid and results in bioaccumulation of lipid-bound bromine in the body at doses relevant to human exposure. To account for uncertainty in translating animal studies to humans, risk assessors evaluate the safety of food ingredients in animal studies at use levels greater than probable human dietary exposure. For example, FDA typically requires food additives to be safe in animal studies at exposures at least 100-fold higher than probable human dietary exposure (21 CFR 170.22) to account for uncertainty in applying results from animal studies to humans. Using the combined 2015–2018 National Health and Nutrition Examination Survey and the conservative assumption that all beverages labeled as containing BVO contain the 15 ppm use level permitted by § 180.30, we estimated mean and 90th percentile dietary exposures of 5 and 9 milligrams (mg) BVO/person (p)/day (d) for the U.S. population aged 2 years and older (Ref. 5), or 0.08 and 0.15 mg/kilogram (kg) body weight (bw)/d on a 60 kg bw basis. The doses of BVO used in the published studies more closely approximate levels of dietary exposure to BVO in humans than the doses used in many of the earlier studies.

NCTR's first 90-day study conducted in rats described adverse effects on the thyroids of test animals following dietary exposure to BVO. Histological changes in the thyroid, specifically follicular cell hypertrophy, were observed in males at all exposure levels and in females at the highest exposure level, suggestive of a sex-specific effect. The incidence of abnormal histopathological findings in male thyroids increased in a dose-dependent manner. This study also demonstrated alterations in hormone signaling along the hypothalamic-pituitary-thyroid axis as a result of dietary exposure to BVO (Ref. 6). Overall, these new data corroborate previous studies in rats and pigs that also reported thyroid toxicity after dietary exposure to BVO (Ref. 3). Additionally, in both studies, dietary exposure to BVO led to the accumulation of inorganic and organic bromine in test animals (Ref. 6), a finding previously related to the onset of central nervous system toxicity (*i.e.,* lethargy, ataxia, and disorientation) in pigs exposed to BVO (Ref. 3). After 90 days of dietary exposure to BVO, accumulation had not reached steady state, but brominated fatty acids appeared to accumulate in a dose-dependent manner in the heart, liver, and inguinal fat of all animals fed BVO.

Based on these study results, we estimated that bioaccumulated brominated fatty acids could persist in test animals for up to 587 days after BVO was removed from the diet (Ref. 6). The observed potential for brominated fatty acids to bioaccumulate in these studies confirms previous studies in laboratory animals and humans that raised safety questions with BVO's use as a food ingredient (Ref. 3). Importantly, the bioaccumulation of lipid-bound bromine makes it difficult to estimate cumulative dietary exposure to BVO and to interpret subchronic studies that reported no adverse effect from dietary exposure to BVO (Ref. 6). These studies demonstrate BVO consumption can result in thyroid toxicity in both male and female rats, interference with the hypothalamic-pituitary-thyroid axis in male rats, and bioaccumulation of lipid-bound bromine in both sexes. These studies demonstrated adverse effects in animals at all doses tested, and the test doses

more closely approximated levels of dietary exposure to BVO in humans than many earlier studies. We could not derive a safe level of dietary exposure to BVO from these studies. As a result of these new data, we concluded that there is no longer a reasonable certainty of no harm from the use of BVO as a stabilizer for flavoring oils in fruit-flavored beverages. Therefore, in the **Federal Register** of November 3, 2023 (88 FR 75523), we issued a proposed rule to revoke the authorization of BVO as a food additive.

B. Summary of Comments to the Proposed Rule

We received over 40 comments to the proposed rule. All comments supported revoking authorization for the use of BVO as an ingredient in food, although some comments asked that we take action against other substances, such as color additives, preservatives, and ''harmful'' chemicals. We discuss the comments later in this final rule.

IV. Legal Authority

We are issuing this final rule under sections 409(i) and 701(a) of the FD&C Act. The FD&C Act defines ''food additive,'' in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component of food, if such substance is not generally recognized by qualified experts as safe under the conditions of its intended use (section 201(s) of the FD&C Act (21 U.S.C. 321(s))). Section 409(i) of the FD&C Act provides that the procedure by which food additive regulations may be amended or repealed are to be prescribed by FDA regulation and that such procedure must conform to the procedure specified in the statute for promulgating these regulations. Under 21 CFR 171.130(a), FDA may propose repealing a regulation pertaining to a food additive. Section 701(a) of the FD&C Act provides the authority to issue regulations for the efficient enforcement of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

We received over 40 comments on our proposal to revoke the authorization for use of BVO as an ingredient in food and are finalizing it without change. The comments came from individuals, a grocery chain, a consumer advocacy group, and an environmental group.

We describe and respond to the comments in this section. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received.

(Comment 1) The proposed rule would revoke § 180.30, which authorizes on an interim basis the use of BVO as a stabilizer for flavoring oils used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 ppm in the finished beverage.

All comments supported revoking BVO's authorization for use as a stabilizer for flavoring oils used in fruit-flavored beverages, and some comments stated that BVO should not be present in foods generally. Most comments supported revocation without offering any additional evidence or summarized the evidence that we gave in the proposed rule. Some comments cited other published articles or made additional arguments to support revocation.

(Response 1) We appreciate interest in and support of the proposed rule. We are finalizing the rule as proposed.

We note that, while some comments said BVO should not be present in food generally, § 180.30 did not authorize BVO's use in all foods. The authorization was specific to BVO's use, on an interim basis, as a stabilizer for flavoring oils used in fruit-flavored beverages. We previously determined that the use of BVO in food is not GRAS (35 FR 1049). Therefore, BVO cannot be used in food without an authorizing food additive regulation or an applicable exception from regulation as a food additive (*e.g.,* section 201(s)(1) through (6) of the FD&C Act).

(Comment 2) Several comments sought actions in addition to revoking § 180.30. In general, the comments asked us to ''ban'' other food and color additives and unspecified ''poisons and toxins.''

(Response 2) The rulemaking, as well as the administrative record supporting the rule, are specific to BVO. Consequently, requests that we take action against other substances are outside the scope of this rulemaking.

We do note, however, that reassessing the safety of substances used in food is an important part of our food safety mission, especially as new information becomes available. See *https://www.fda.gov/news-events/fda-voices/how-fdas-new-approach-reviewing-chemicals-added-food-will-strengthen-food-safety.*

(Comment 3) One comment said that our conclusions regarding BVO's safety probably would extend to other brominated food additives and asked that we evaluate brominated food additives as a group and ensure that consumers are not exposed to bromine-related health risks through other means once BVO is no longer permitted as a food additive. The comment also asked that we revoke the authorization for all brominated vegetable oils, including brominated soybean oil.

(Response 3) With respect to brominated soybean oil, within § 180.30, the term ''brominated vegetable oil'' includes any vegetable oil subjected to bromination, as described in section I.A. of this document. Because this rulemaking revokes § 180.30, a vegetable oil subjected to bromination (including brominated soybean, corn, cottonseed, olive, and sesame oil) is no longer authorized for use as a stabilizer for flavoring oils used in fruit-flavored beverages.

With respect to other brominated food additives, this request is outside the scope of this rulemaking.

(Comment 4) Two comments stated that while some manufacturers already have discontinued use of BVO, products containing BVO are available on the market and found in store-brand products and ''lesser-known regional brand'' products or ''value products'' sold in low-budget stores. The comments said that people with limited income are more likely to buy such products and, therefore, will be more likely to suffer adverse health effects.

(Response 4) We agree with the comments. In addition, as noted in the economic analysis accompanying the rule, BVO-containing beverages are often sugar-sweetened beverages, and some studies show that low-income consumers may consume more sugar-sweetened beverages and thus may be disproportionately exposed to BVO. Also, as noted in the economic analysis accompanying the proposed rule, news about manufacturers committing to removing BVO has been prevalent in the past decade, which may lead to consumers spending less time reading food product labels to determine whether food contains BVO. This would potentially create an information asymmetry where consumers incorrectly believe that their food no longer contains BVO. Thus, intervention is needed to avoid potential adverse health impacts in the shorter term.

VI. Description of the Final Rule

The final rule revokes § 180.30, which authorizes on an interim basis the use of BVO as a stabilizer for flavoring oils generally used in fruit-flavored beverages, for which any applicable standards of identity do not preclude such use, in an amount not to exceed 15 ppm in the finished beverage. We previously determined that the use of BVO in food is not GRAS (35 FR 1049). Therefore, the use of BVO in food is no longer be authorized.

VII. Effective/Compliance Dates

The final rule's effective date is August 2, 2024.

We also recognize that the food industry would need sufficient time to reformulate products and for these products to work their way through distribution. Therefore, the compliance date for this rule is 1 year after the effective date, to provide the opportunity for companies to reformulate, relabel, and deplete the inventory of BVO-containing products before we begin enforcing the final rule.

VIII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601–612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this final rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that this final rule will impact at most 2.5 percent of small businesses within the beverage manufacturing industry, and because we believe that costly disruptions to small entities are likely to be small due to replacement formulas for BVO having been in place and widely used for decades, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

Food producers would not be permitted to use BVO as a food additive under the final rule. For the purposes of this analysis, we assume that all products currently using BVO will be reformulated to use some other kind of stabilizer.

The costs of this final rule come from reformulating products currently manufactured with BVO, relabeling products currently manufactured with BVO, ingredient substitutes for BVO, and changes to sensory product properties. The benefits of this final rule come in the form of public health gains from reduced exposure to BVO. The annualized costs (with a discount rate of 2 percent) of this rule, minus the costs of the baseline of gradual voluntary reduction, are $0.02 million to $0.06 million. The first-year costs of the final rule are $6.6 million to $16.4 million. We estimate the annualized reduction in BVO exposure under the final rule relative to the baseline of gradual voluntary reduction to be roughly 0.02 million oz.

It is possible that the cost of reformulation and relabeling could be passed on to consumers in the form of higher prices. We do not know what percentage of the costs will be passed on to consumers. However, replacement formulas have been in place for decades and are widely used in beverage products throughout the United States and the world. The time between the publication of our final rule and the rule's compliance period should minimize costly disruptions to manufacturers still using BVO.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE

[Millions of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes (*e.g.,* risk assumptions; source citations; whether inclusion of capital effects differs across low, primary, high estimates; etc.)
Benefits:							
Annualized monetized benefits.	.....	.....	.....	.....	2	.....	
Annualized quantified, but non-monetized, benefits.	0.02 million oz	0.01 million oz	0.03 million oz	.....	.....	2026–2045	The benefits of the final rule come in the form of reduction in exposure to BVO.
Unquantified benefits	.....	.....	.....	.....	.....	.....	For the rule to be cost effective, it would have to prevent over $2 worth of illness annually per oz of reduced BVO exposure.
Costs:							

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF THE FINAL RULE—Continued
[Millions of 2023 dollars]

Category	Primary estimate	Low estimate	High estimate	Dollar year	Discount rate (%)	Time horizon	Notes (*e.g.,* risk assumptions; source citations; whether inclusion of capital effects differs across low, primary, high estimates; etc.)
Annualized monetized costs.	$0.04 million/yr	$0.02 million/yr	$0.06 million/yr	2023	2	2026–2045	The first-year costs are roughly $6.6 million to $16.4 million.
Annualized quantified, but non-monetized, costs.	.....	.....	.....	.....	.....	.....	
Unquantified costs	.....	.....	.....	.....	.....	.....	
Transfers:							
Annualized monetized Federal budgetary transfers.	.....	.....	.....	.....	2	.....	
Bearers of transfer gain and loss?.	.....	.....	.....	.....	.....	.....	
Other annualized monetized transfers.	.....	.....	.....	.....	2	.....	
Bearers of transfer gain and loss?.	Consumers	.....	.....	.....	.....	.....	We do not know what percentage of producer costs will be passed on to consumers.
Net Benefits:							
Annualized monetized net benefits.	.....	.....	.....	.....	2	.....	

Category	Effects	Notes
Effects on State, local, or Tribal governments.		
Effects on small businesses ..	No significant impact on substantial number of small businesses.	In the Small Entity Analysis, we estimate that this final rule does not have a significant economic impact on a substantial number of small businesses.
Effects on wages		
Effects on growth		

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 7) and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

We received comments on our preliminary regulatory impact analysis of the proposed rule. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or the order in which it was received.

(Comment 5) One comment said that banning of BVO is supported economically, socially, and scientifically in both the USA as well as many other countries in the world, and that the economic impact of such a ban would be minor especially with the ease of access to safer substitutes.

(Response 5) We appreciate interest in and support of the proposed rule. The preliminary regulatory impact analysis supports the comment's conclusion that the economic impact of banning BVO would be minor, and this is also supported in our final regulatory impact analysis.

(Comment 6) One comment said that products containing BVO are available on the market and disproportionately expose low-income consumers to health risks.

(Response 6) The distributional analysis section of the preliminary regulatory impact analysis and of the final regulatory impact analysis presents recent statistics and studies showing differential consumption of sugar-sweetened beverages. Some of these statistics and studies concur with the comment's conclusion that low-income consumers are disproportionately exposed to BVO.

(Comment 7) One comment said that, even if the cost to transition to BVO alternatives had been determined to be untenable, BVO should still be banned.

(Response 7) Given that no comments opposed revoking § 180.30 or argued for any other action (such as amending the rule), and given FDA's determination that there is no longer a basis to conclude that this use of BVO is safe, we have finalized the rule by revoking § 180.30.

IX. Analysis of Environmental Impacts

We previously considered the environmental effects of this rule, as stated in the proposed rule (88 FR 75523 at 75527). We stated that we had determined, under 21 CFR 25.32(m), that this action ''is of a type that does not individually or cumulatively have a significant effect on the human environment'' such that neither an environmental assessment nor an environmental impact statement is required. We did not receive any new information or comments that would affect our previous determination.

X. Paperwork Reduction Act of 1995

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

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would have a

substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XIII. 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. FDA Memorandum from S. Shibko to Division of Regulations and Petitions Control, May 25, 1970.

*2. FDA Memorandum from L. Friedman to L. Buckley, Division of Regulations and Petitions Control, October 21, 1970.

*3. FDA Memorandum from Y. Zang to T. Croce, Division of Petition Review, September 2, 2014.

4. Woodling K.A., P. Chitranshi, C.C. Jacob, et al., ''Toxicological Evaluation of Brominated Vegetable Oil in Sprague Dawley Rats.'' *Food and Chemical Toxicology,* 165:113137, 2022.

*5. FDA Memorandum from D. Doell to J. Downey, Regulatory Review Branch—Team 1, March 1, 2023.

*6. FDA Memorandum from J. Gingrich to J. Downey, Regulatory Review Branch—Team 1, March 1, 2023.

*7. FDA Final Rule to Revoke Uses of Brominated Vegetable Oil in Foods (*https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations*).

List of Subjects in 21 CFR Part 180

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 180 is amended as follows:

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

§ 180.30 [Removed]

■ 2. Remove § 180.30.

Dated: June 18, 2024.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2024–14300 Filed 7–2–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 58

[TD 10002]

RIN 1545–BQ60

Excise Tax on Repurchase of Corporate Stock—Procedure and Administration

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance regarding the reporting and payment of the excise tax on repurchases of corporate stock made after December 31, 2022. The regulations affect certain publicly traded corporations that repurchase their stock or whose stock is acquired by certain specified affiliates.

DATES:

Effective date: These final regulations are effective on June 28, 2024.

Applicability dates: For dates of applicability, *see* §§ 58.6001-(d), 58.6011–1(d), 58.6060–1(b), 58.6061–1(b), 58.6065–1(b), 58.6071–1(e), 58.6091–1(d), 58.6107–1(b), 58.6109–1(b), 58.6151–1(b), 58.6694–1(e), 58.6695–1(b), and 58.6696–1(b).

SUPPLEMENTARY INFORMATION:

Background

I. The Proposed Regulations

On April 12, 2024, the Department of the Treasury (Treasury Department) and the IRS published proposed regulations (REG–118499–23) in the **Federal Register** (89 FR 25829) that would provide rules on procedure and administration applicable to the reporting and payment of the excise tax on repurchases of corporate stock (stock repurchase excise tax) imposed by section 4501 of the Internal Revenue Code (Code) for repurchases made after December 31, 2022 (proposed procedural regulations). This Treasury decision finalizes the proposed procedural regulations (other than proposed § 58.6011–1(c)) after taking into account comments received, as described in the Summary of Comments and Explanation of Revisions section of this preamble. The final regulations are added as subpart B of new 26 CFR part 58 (Stock Repurchase Excise Tax Regulations), which is added to subchapter D of 26 CFR chapter I (Miscellaneous Excise Taxes).

On April 12, 2024, the Treasury Department and the IRS also published a separate notice of proposed rulemaking (REG–115710–22) in the same issue of the **Federal Register** (89 FR 25980) that would provide operating rules in proposed subpart A of part 58 relating to the computation of the stock repurchase excise tax (proposed computational regulations). This Treasury decision does not finalize the proposed computational regulations. The Treasury Department and the IRS intend to finalize the proposed computational regulations in a separate Treasury decision after considering comments received with respect to those proposed regulations.

II. Section 4501; Notice 2023–2

Section 4501 was added to a new chapter 37 of the Code by the enactment of section 10201 of Public Law 117–169, 136 Stat. 1818 (August 16, 2022), commonly referred to as the Inflation Reduction Act of 2022 (IRA). In general, section 4501 imposes the stock repurchase excise tax on each covered corporation (as defined in section 4501(b)) for repurchases made after December 31, 2022. *See* section 10201(d) of the IRA. The stock repurchase excise tax is equal to 1 percent of the fair market value of any stock of the covered corporation that is