

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 2001C–0486] (formerly Docket No. 01C–0486)

Listing of Color Additives Exempt From Certification; Tomato Lycopene Extract and Tomato Lycopene Concentrate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections; removal of stay.

SUMMARY: The Food and Drug Administration (FDA) is responding to two objections that it received on the final rule that amended the color additive regulations authorizing the use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods. After reviewing the objections to the final rule, the agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for modifying the amendment to the regulation. FDA is also establishing a new effective date for this color additive regulation, which was stayed by the filing of proper objections.

DATES: The final rule that published in the **Federal Register** of July 26, 2005 (70 FR 43043), with an effective date of August 26, 2005, was stayed by the filing of objections as provided for under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)(2)) as of August 25, 2005. This final rule is newly effective as of [*insert date of publication in the **Federal Register***].

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SUPPLEMENTARY INFORMATION:

I. Introduction

FDA published a notice in the **Federal Register** on October 30, 2001 (66 FR 54773), announcing the filing of a color additive petition (CAP 1C0273) by LycoRed Natural Products Industries to amend the color additive regulations in part 73 (21 CFR part 73) to provide for the safe use of tomato lycopene extract to color foods generally. The petition included information on two forms of tomato lycopene (extract and concentrate) that differ primarily in concentration. In the **Federal Register** of July 26, 2005 (70 FR 43043), the agency issued a final rule providing for the safe use of tomato lycopene extract and tomato lycopene concentrate as color additives in foods. The preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by August 25, 2005) and that the rule would be effective on August 26, 2005, except that any provisions may be stayed by the filing of proper objections.

II. Objections and Requests for a Hearing

Sections 701(e)(2) and 721(d) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2) and 379e(d)) 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 reasonable grounds therefore, and requesting a public hearing based upon such objections.”

Objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA’s regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state the provision of the regulation or proposed order 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) must 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 publication of the final rule, FDA received two objections within the 30-day objection period. Neither objection requested a hearing; therefore a hearing has been waived (21 CFR 12.22(a)(4)). One objection asserted that lycopene extracted from tomatoes “could trigger more individuals to become allergic to tomatoes and could even become life threatening through anaphylactic shock to those of us who have severe allergies.” As an alternative to revoking the regulation, the submission proposed that lycopene extracted from tomatoes “must be labeled as such.” The second objection requested that the scope of the regulation be broadened to include the use of lycopene isolated from other plant sources, such as watermelon, as a color additive in foods.

III. Analysis of Objections

FDA addresses each of the two objections in the following paragraphs, as well as the evidence and information filed in support of each.

One submission objected to the final rule, asserting that people who have a severe tomato allergy may experience an allergic reaction to lycopene extracted from tomatoes and that exposure to lycopene extracted from tomatoes may cause sensitive individuals to develop an allergy to tomatoes. The objector did not provide reliable data and information to support the assertion that sensitive individuals will exhibit an allergic reaction to lycopene extracted from tomatoes. The objector also did not provide evidence that sensitive individuals may develop an allergy to tomatoes from exposure to lycopene extracted from tomatoes. Therefore, the submission provided no information that would support a reevaluation of the agency's safety analysis of lycopene extracted from tomatoes. FDA concludes that this submission provides no basis for the agency to reconsider its decision to issue the final rule on the use of lycopene extract and concentrate as a color additive in food. Therefore, FDA is denying this objection (§ 12.24(b)(3)).

The second objection requested that FDA broaden the scope of the regulation to include the use of lycopene isolated from other plant sources, such as watermelon, as an additive in foods. FDA is denying this objection because the request is inconsistent with the act and FDA's regulations (§ 12.24(b)(5)). If the submitter desires to expand the uses covered by the lycopene regulation, the proper course is to file a separate petition to amend the lycopene color additive regulation, meeting all requirements for such a petition (e.g., 21 CFR part 71).

IV. Summary and Conclusions

The agency is denying the objections on the following grounds: (1) The submission based on an allergy to tomato-derived lycopene does not include evidence that calls into question FDA's conclusion that the use of lycopene

extracted from tomatoes is safe for use as a color additive in foods and (2) the request to include under § 73.585 lycopene extracted from other plant sources, such as watermelon, is beyond the scope of the petitioned action for tomato-derived lycopene and is appropriately resolved through the submission of a separate petition.

The filing of the objections served to stay automatically the effectiveness of § 73.585. Section 701(e)(2) of the act states that “Until final action upon such objections is taken by the Secretary * * *, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made.” Section 701(e)(3) of the act further provides that “as soon as practicable * * *, the Secretary shall by order act upon such objections and make such order public.”

The agency has completed its evaluation of the objections and concludes that a continuation of the stay of this regulation is not warranted.

In the absence of any other objections and requests for a hearing, the agency, therefore, further concludes that this document constitutes final action on the objections received in response to the regulation as prescribed in section 701(e)(2) of the act. Therefore, the agency is acting to end the stay of the regulation by establishing a new effective date of [*insert date of publication in the **Federal Register***] for this regulation, listing tomato lycopene extract and tomato lycopene concentrate as color additives in foods. As announced in the **Federal Register** of July 26, 2005 (70 FR 43043), the previous effective date of the regulation was August 26, 2005.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, notice is given

that the objections filed in response to the final rule that was published on July 26, 2005 (70 FR 43043), do not form the basis for further stay of this final

rule or require amendment of the regulations. Accordingly, the stay of § 73.585 that FDA is announcing in this document, is removed effective [*insert date of publication in the **Federal Register***].

Date: February 16, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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