regulations by listing the color additive for use in contact lenses.

VI. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the use of the color additive in contact lenses are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in 21 CFR 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Considerations

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. FDA's regulations implementing the National Environmental Policy Act (21 CFR Part 25) have been replaced by a rule published in the **Federal Register** of April 26, 1985 (50 FR 16636, effective July 25, 1985). Under the new rule, an action of this type would require an environmental assessment under 21 CFR 25.31a(a).

VIII. Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1986 file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register.**

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR Part 73 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

2. By adding new § 73.3124 to Subpart D, to read as follows:

§ 73.3124 Phthalocyanine green.

(a) *Identity.* The color additive is phthalocyanine green (CAS Reg. No. 1328–53–6), Colour Index No. 74260.

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used as a color additive in contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

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

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

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore the color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: March 26, 1986.

M.D. Kinslow,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–7366 Filed 4–2–86; 8:45 am]

BILLING CODE 4160–01–M

21 CFR Part 145

[Docket No. 77P–0300]

Canned Peaches; Amendment of Standard of Quality; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date for compliance with the final rule amending the standard of quality for canned peaches published in the **Federal Register** of August 27, 1985 (50 FR 34676).

EFFECTIVE DATE: Effective July 1, 1987, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may have begun October 28, 1985.

FOR FURTHER INFORMATION CONTACT: Howard A. Anderson, Center for Food Safety and Applied Nutrition (HFF–214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0118.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of August 27, 1985 (50 FR 34676), FDA amended the standard of quality for canned peaches (21 CFR 145.170(b)) to include (1) a uniformity of size requirement for whole, halves, and quarter styles based on the diameter of the units; (2) a limitation on pits and pieces of pits; and (3) requirements for chunky style. The final rule was promulgated in consideration of the quality provisions of the Recommended International Standard for Canned Peaches, First Revision, 1975 (CAC/RS 14–1969) (Codex standard) and petitions by Libby, McNeill & Libby, Inc., California League of Food Processors, and the Food Safety and Quality Service, United States Department of Agriculture. The final rule provided that any person who would be adversely affected could, at any time on or before September 26, 1975, file written objections and request a hearing on the specific provisions to which there were objections.

Objections and Requests for a Hearing

Six objections and requests for a hearing were filed in regard to the requirement (21 CFR 145.170(b)(1)(vii)) that in the case of "halves and pieces," not more than 5 percent by count of the units in containers of 20 or more units and not more than 1 unit in containers of

fewer than 20 units are crushed or broken. The objections asserted that manufacturers could not meet the requirement limiting the number of crushed or broken units permitted in a container because the fruit grown in the southeastern part of the United States, which must be picked very ripe in order to secure the best color and flavor, is very soft and is easily broken during the canning process, especially during filling of the cans.

The objections appear to arise from a misreading of the final rule. The requirement in question does not apply to the factual circumstances that are the subject of the objections. In fact, the final rule specifically provides that a "unit that has lost its normal shape because of ripeness and bears no mark of crushing shall not be considered crushed or broken." See 21 CFR 145.170(b)(1)(vii). Therefore, no issue of fact has been raised by the objections. Accordingly, the agency is denying the requests for hearing.

List of Subjects in 21 CFR Part 145

Canned fruits, Food standards, Fruits.

PART 145—CANNED FRUITS

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Food Safety and Applied Nutrition (21 CFR 5.62), notice is given that Part 145, as amended in the **Federal Register** of August 27, 1985 (50 FR 34676), will become effective July 1, 1987. Voluntary compliance may have begun October 28, 1985.

Dated: March 18, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-7367 Filed 4-2-86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 160

[Docket No. 85P-0028/CP]

Lysozyme and Avidin Reduced Dried Egg Whites; Amendment of the Standard of Identity

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the U.S. standard of identity for dried egg white to provide for the optional reduction of lysozyme and avidin content by cation exchange procedures before drying. The purpose of this action, based upon a petition filed on behalf of two food ingredient producers, is to promote honesty and fair dealing in the interest of consumers by allowing increased flexibility in the use of certain food ingredients.

DATES: Effective July 1, 1987, all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date shall fully comply. Except as to any provisions that may be stayed by the filing of proper objections, voluntary compliance with this final regulation, including any required labeling changes, may begin June 2, 1986. Objections by May 5, 1986. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 160.145 effective June 2, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Arthur R. Johnson, Center for Food Safety and Applied Nutrition (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 201-485-0112.

SUPPLEMENTARY INFORMATION:

Background

In the **Federal Register** of August 27, 1985 (50 FR 34721), FDA published a notice of proposed rulemaking to amend the standard of identity for dried egg whites (21 CFR 160.145) to provide for the optional reduction of lysozyme and avidin content by cation exchange procedures before drying. This proposed action was based upon a petition, dated January 17, 1985, filed on behalf of Societa Prodotti Antibiotici and Henningsen Foods, Inc. The petitioners submitted data demonstrating that lysozyme and avidin reduced dried egg whites obtained by the procedures described are not nutritionally or functionally inferior to currently standardized egg whites.

Interested persons were given until October 28, 1985, to submit comments regarding the proposal.

FDA received three comments on the proposal. All supported the proposed amendment.

One comment suggested additional wording to § 160.145(e) to clarify that the phrase "lysozyme and avidin reduced" may be omitted from any declaration of ingredients when the dried egg whites are used as an ingredient in a fabricated food.

FDA agrees with this comment and has revised § 160.145(e) accordingly.

Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96-354 (5 U.S.C. 601)), FDA has considered the effect that this final rule would have on small entities including small businesses and has determined that this final rule would have no adverse effect because, based on the comments received, industry considers these requirements, as revised, to be current good manufacturing practices. Therefore, FDA certifies that this action will not have a significant economic impact on a substantial number of small entities.

Objections

Any person who will be adversely affected by this regulation may at any time on or before May 5, 1986 submit to the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Received objections may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 160

Eggs, Food standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 160 is amended as follows:

PART 160—EGGS AND EGG PRODUCTS

1. The authority citation for 21 CFR Part 160 is revised to read as follows:

Authority: Secs. 401, 701, 52 Stat. 1046, 1055–1056 as amended (21 U.S.C. 341, 371); 21 CFR 5.10, 5.61.

2. In § 160.145 by revising paragraph (a), by redesignating paragraph (c) as paragraph (d), and by adding new paragraphs (c) and (e), to read as follows:

§ 160.145 Dried egg whites.

(a) The food dried egg whites, egg white solids, dried egg albumen, egg albumen solids is prepared by drying liquid egg whites conforming to the requirements of § 160.140 (or deviating from that section only by not being *Salmonella* free). As a preliminary step to drying, the lysozyme and avidin contents may be reduced. If lysozyme and avidin levels are reduced, cation exchange resins regulated for use under § 173.25 of this chapter shall be used. As a further preliminary step to drying, the glucose content of the liquid egg whites is reduced by adjusting the pH, where necessary, with food-grade acid and by following one of the optional procedures set forth in paragraph (b) of this section. If the food is prepared from liquid egg whites conforming in all respects to the requirements of § 160.140, drying shall be done with such precautions that the finished food is free of viable *Salmonella* microorganisms. If the food is prepared from liquid egg whites that are not *Salmonella* free, the dried product shall be so treated by heat or otherwise as to render the finished food free of viable *Salmonella* microorganisms. Dried egg whites may be powdered.

* * * * *

(c)(1) Dried egg whites in which the lysozyme and avidin have been reduced shall not be nutritionally inferior, as defined in § 101.3(e)(4)(i) of this chapter, and shall be considered nutritionally equivalent to untreated egg whites if they meet the conditions that the biological quality of the protein contained is equal to or greater than that of untreated egg white from the same batch of liquid egg white.

(2) Compliance with the biological quality of protein requirement of paragraph (c)(1) of this section shall be determined by the analytical method prescribed in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th Ed. (1984), section 43.253–43.257, "Protein Efficiency Ratio, Rat Bioassay, Final Action," which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists, Box 540, Benjamin Franklin Station, Washington, DC 20044, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

* * * * *

(e) The name of the food for which a definition and standard of identity is prescribed in this section is alternatively "Dried egg whites", Egg white solids", "Dried egg albumen", or "Egg albumen solids". If the lysozyme and avidin content is reduced as provided in paragraph (a) of this section, the name shall be immediately preceded or followed by the statement "lysozyme and avidin reduced" when the dried egg whites are sold as such. When the dried egg whites are used in a fabricated food, the statement "lysozyme and avidin reduced" may be omitted from any declaration of ingredients required under § 101.4 of this chapter.

Dated: March 24, 1986.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–7368 Filed 4–2–86; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 73

[Docket No. 83C–0051]

Listing of Color Additives for Coloring Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of an orange dye, 6-ethoxy-2-(6-ethoxy-3-oxobenzo[*b*]thien-2-(3*H*)-ylidene)benso[*b*]thiophen-3-(2*H*)-one, for coloring contact lenses. This action responds to a petition filed by Custom Tint Laboratories, Inc.

DATES: Effective May 6, 1986, except as to any provisions that may be stayed by the filing of proper objections; objections by May 5, 1986.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rudolph Harris, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of June 17, 1983 (48 FR 27834), FDA announced that a color additive petition (CAP 3C0169) had been filed by Custom Tint Laboratories, Inc., 6020 Six Forks Rd., Raleigh, NC 27609, proposing that the color additive regulations be amended to provide for the safe use of six color additives, including an orange dye, 6,6'-diethoxy-2,2'-[3*H*,3'H]dibenzo-[*b*]thiophene-3,3'-dione, for coloring contact lenses. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

In the **Federal Register** of July 8, 1983 (48 FR 31374), FDA amended the color additive regulations by listing four of the color additives that were the subject of the June 17, 1983, notice. In the July 8, 1983, document, as corrected in the **Federal Register** of September 28, 1983 (48 FR 44202), FDA deferred the listing of the two other dyes. In the **Federal Register** of May 16, 1985 (50 FR 20405), FDA issued a final rule listing the fifth color additive, C.I. Vat Orange 1 (referred to by the agency as dibromodibenzo(*b, def*)chrysene-7, 14-dione).

This document announces FDA's decision on the listing of the sixth color additive. Although the additive was described by the chemical name 6,6'-diethoxy-2,2'-[3H,3'*H*]dibenzo-[*b*]thiophene-3,3'-dione in the notice of filing and in subsequent documents on these color additives, the agency has discovered during its review that the additive is identified as 6-ethoxy-2-(6-ethoxy-3-oxobenzo[*b*]thien-2-(3*H*)-ylidene)benzo[*b*]thiophen-3(2*H*)-one in the Chemical Abstracts Service (CAS) Registry Handbook. To be consistent with the CAS Registry Handbook, the agency is adopting the CAS name and number (CAS Reg. No. 3263–31–8) for this dye in this final rule.

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 to the act (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices where the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of this material as a color additive in contact lenses is subject to regulation under the act. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for