

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

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

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-(3H)-ylidene)benzo[b]thiophen-3-(2H)-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'-[3H,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-(3H)-ylidene)benzo[b]thiophen-3-(2H)-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

several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive presently before the agency is subject to the statutory listing requirement.

III. Analysis of Data

To establish that the color additive, 6-ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one, is safe for use in coloring contact lenses, the petitioner submitted various toxicity data. In a primary ocular irritation study in rabbits, there was no ocular irritation from saline extracts of the tinted lens material.

The petitioner also conducted cytotoxicity studies of tinted lens materials using the human epitheloid carcinoma cell line HEP-2. No adverse effects were found in these cytotoxicity studies.

The agency also calculated the upper limit of exposure to be 270 nanograms per day based on the following two factors. First, based on the information submitted by the petitioner, FDA estimated that the maximum use level of the color additive is 50 micrograms per lens. See, Memorandum of February 19, 1985, from Food Additive Chemistry Evaluation Branch to Petitions Control Branch, Re: Color Additives in Contact Lenses, which is on file in the Dockets Management Branch (address above) under the docket number appearing in the heading of this document and is available for public review between 9 a.m. and 4 p.m., Monday through Friday. Second, the agency made two worst-case assumptions:

(1) That the user will replace lenses tinted with the color additive once each year with a new pair of lenses tinted with the color additive at the maximum use level; and (2) that 100 percent of the color additive migrates from the lenses over the 1-year period. Because these assumptions are a worst-case estimate, exposure to this color additive from its use for coloring contact lenses is likely to be far less than 280 nanograms per day. In the case of this color additive, no cytotoxic effect was observed at a concentration many times greater than the concentration that would be in the eyes if 270 nanograms of the dye migrated into the eyes per day.

IV. Certification Considerations

Based on its review of relevant data, FDA concludes that the safety margin for use of this color additive is large enough to rule out any need for imposing a limitation on the amount of the color additive that may be present in the lens, beyond the limitation that only the

amount necessary to accomplish the intended technical effect may be used. Also, based on its consideration of the factors listed in § 71.20(b) (21 CFR 71.20(b)), the agency concludes that certification of the color additive listed in this final rule is not necessary for the protection of the public health.

V. Conclusion

Based on the data contained in the petition and other relevant material, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of 6-ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene) benzo [b] thiophen-3(2H)-one for coloring contact lenses. The agency further concludes on the basis of data contained in the petition that this color additive is suitable for its intended use. The agency, therefore, is amending 21 CFR Part 73 of the color additive regulations by listing this 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 petition 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 § 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 § 73.3123 to Subpart D, to read as follows:

§ 73.3123 6-Ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one.

(a) *Identity.* The color additive is 6-ethoxy-2-(6-ethoxy-3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophen-3(2H)-one (CAS Reg. No. 3263-31-8), Colour Index No. 73335.

(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 color 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. 86-7364 Filed 4-2-86; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

21 CFR Part 193

[FAP 5H5462/R816, (FRL-2996-3)]

Pesticide Tolerance for 3-(3, 5-Dichlorophenyl)-5-Ethenyl-5-Methyl-2, 4-Oxazolinedione

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a food additive regulation for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolinedione (referred to in the preamble of this document as vinclozolin) and its 3,5-dichloroaniline containing metabolites in or on the food commodity prunes. This regulation to establish the maximum permissible level for residues of the fungicide in or on prunes was requested by BASF Wyandotte Corp.

EFFECTIVE DATE: Effective on April 3, 1986.

ADDRESS: Written objection, identified by the document control number [FAP 5H5462/R816], may be submitted to the Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: By mail: Henry M. Jacoby, Product Manager (PM) 21, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 227, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202 (703-557-1900).

SUPPLEMENTARY INFORMATION: EPA issued a proposed rule, published in the **Federal Register** of January 29, 1986 (51 FR 3632), that announced that BASF Wyandotte Corp., submitted food additive petition 5H5462 to the Agency proposing to amend 21 CFR Part 193 by establishing a regulation permitting the combined residues of the fungicide vinclozolin and its 3,5-dichloroaniline containing metabolites in or on the commodity dried prunes at 75.0 ppm.

There were no comments or request for referral to an advisory committee received in response to the proposed rule.

A related document [PP 2F2650/R815], establishing a tolerance on stonefruits, appears elsewhere in this issue of the **Federal Register**.

The data submitted and other relevant information in support of the tolerance have been evaluated and discussed in the **Federal Register** of January 29, 1986 (51 FR 3635). Based on the information and data considered, the Agency concludes that the pesticide can be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (86 Stat. 973, 7 U.S.C. 136a *et seq.*) Therefore, the food additive regulation is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections with the Hearing Clerk, at the address given above. Such objections should specify the provisions of the regulation deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

List of Subjects in 21 CFR Part 193

Food additives, Pesticides and pests.

Dated: March 17, 1986.

Steven Schatzow,

Director, Office of Pesticide Programs.

Therefore, 21 CFR Part 193 is amended as follows:

PART 193—[AMENDED]

1. The authority citation for Part 193 continues to read as follows:

Authority: 21 U.S.C. 348.

2. Section 193.137 is added to read as follows:

§ 193.137 3-(3,5-Dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolinedione.

Tolerances are established for the combined residues of the fungicide 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the following food commodities:

Foods	Parts per million
Prunes...	75

[FR Doc. 86-7415 Filed 4-2-86; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Animal Drugs, Feeds, and Related Products; Hyaluronate Sodium Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of the new animal drug application (NADA) filed by Med-Chem Products, Inc., providing for safe and effective use of hyaluronate sodium injection in treating horses for joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis. The regulations are further amended to add the firm to the list of sponsors of approved NADA's.

EFFECTIVE DATE: April 3, 1986.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Med-Chem Products, Inc., Woburn, MA 01801, is sponsor of NADA 122-578 which provides for intra-articular injection of a 1 percent (10 milligrams per milliliter) solution of hyaluronate sodium (HYVISC™) for treating horses for joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis. The application is