Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2000–15–51 Cessna Aircraft Company: Amendment 39–11850. Docket 2000–NM–255–AD.

Applicability: Model 560XL airplanes, certificated in any category; serial numbers (S/N) –5002 and subsequent.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent interference between the aileron cable fairlead tube and the aileron cable sector, which could result in loss of control of the airplane, accomplish the following:

Pre-modification Inspection

(a) For airplanes having S/N –5002 through –5093 inclusive: Before the next flight after the effective date of this AD, perform a general visual inspection to measure how far the aileron fairlead tube protrudes beyond the clamp at the aft aileron sector. This area of the airplane is depicted in Figure 1 of Cessna Service Bulletin SB560XL–27–10, including Service Bulletin Supplemental Data, dated July 13, 2000. Thereafter, repeat the inspection at intervals not to exceed 5 flight cycles until accomplishment of paragraph (b) of this AD. If, during any inspection required by this paragraph, more than one-half inch of the tube is found to protrude, prior to further flight, accomplish the actions specified by paragraph (b) of this AD.

Note 2: For the purposes of this AD, a general visual inspection is defined as: ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Modification

(b) For airplanes having S/N –5002 through –5093 inclusive: Within 25 flight hours or 30 days after the effective date of this AD, whichever occurs first, modify the aileron fairlead tubes (including trimming the fairlead tube and cementing the clamp to the tube with fuel tank sealer) in accordance with Cessna Service Bulletin SB560XL–27–10, including Service Bulletin Supplemental Data, dated July 13, 2000. Allow 2 hours of cure time before further flight. Accomplishment of the modification terminates the repetitive inspection requirement of paragraph (a) of this AD.

Post-modification Inspection

(c) For all airplanes: At the applicable time specified by paragraph (c)(1) or (c)(2) of this AD, perform a general visual inspection to determine if the fairlead tube is flush with the clamp. This area of the airplane is depicted in Figure 1 of Cessna Service Bulletin SB560XL–27–10, including Service Bulletin Supplemental Data, dated July 13, 2000. If the tube is not flush, prior to further flight, repeat the actions specified by paragraph (b) of this AD, and notify the Manager, Wichita Aircraft Certification Office (ACO), FAA, Mid-Continent Airport, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone (316) 946–4106; fax (316) 946–4407. Repeat the inspection thereafter at intervals not to exceed 110 flight hours.

(1) For airplanes having S/N –5002 through –5093 inclusive: At the next scheduled maintenance or within 110 flight hours after the modification required by paragraph (b) of this AD, whichever occurs first.

(2) For S/N –5094 and subsequent: At the next scheduled maintenance or within 110 flight hours after the effective date of this AD, whichever occurs first.

Alternative Methods of Compliance

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Wichita ACO. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(f) The modification shall be done in accordance with Cessna Service Bulletin SB560XL–27–10, including Service Bulletin Supplemental Data, dated July 13, 2000. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Cessna Aircraft Co., P.O. Box 7706, Wichita, Kansas 67277. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on August 14, 2000, to all persons except those persons to whom it was made immediately effective by emergency AD 2000–15–51, issued on July 19, 2000, which contained the requirements of this amendment.

Issued in Renton, Washington, on July 31, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–19818 Filed 8–7–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 97C–0415]

Listing of Color Additives Exempt From Certification; Luminescent Zinc Sulfide

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of luminescent zinc sulfide as a color additive in certain externally applied cosmetics. This action is in response to a petition filed by Zauder Bros., Inc.

DATES: This rule is effective September 8, 2000; except as to any provisions that may be stayed by the filing of proper objections. Submit written objections and requests for a hearing by September 7, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Aydin O–AE4rstan, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of October 6, 1997 (62 FR 52136), FDA announced that a color additive petition (CAP 7C0251) had been filed by Zauder Bros., Inc., c/o Schiff & Co., 1129 Bloomfield Ave.,

West Caldwell, NJ 07006. The petition proposed to amend the color additive regulations to provide for the safe use of zinc sulfide as a color additive in externally applied cosmetics. During its review of the petition, the agency determined that the subject color additive is zinc sulfide containing an added copper activator that produces a luminescent color. Therefore, the agency is establishing luminescent zinc sulfide as the common or usual name of the color additive.

II. Identity, Technical Effect, and Specifications

Luminescent zinc sulfide is zinc sulfide containing 0.01 weight percent (100 parts per million) copper (Ref. 1). Copper functions as an activator. Following excitation by daylight or a suitable artificial light, luminescent zinc sulfide produces a yellow-green phosphorescence with a maximum at 530 nanometers (Ref. 1). The petitioner intends to use luminescent zinc sulfide in nail polishes and facial creams to produce a ''glow-in-the-dark'' effect.

The luminescent zinc sulfide that is the subject of the petition contains $100_{\pm}5$ parts per million copper. To ensure that the color additive in finished products contains an effective level of copper consistent with the material identified in the petition, the agency is establishing the range of copper as $100_{\#}5$ parts per million in new § 73.2995(b).

In addition to copper, other activators, for example cobalt, may also be added to zinc sulfide to obtain pigments with different phosphorescent properties (Ref. 1). However, the petitioner did not request the listing of zinc sulfide containing activators other than copper and the petition contains no relevant safety data. Therefore, phosphorescent zinc sulfide pigments containing activators other than copper are not covered by this final rule.

III. Safety Evaluation

The petitioner proposed to use luminescent zinc sulfide in nail polishes and specialized facial makeup preparations for use on limited occasions such as Halloween. The agency reviewed the data in the petition and determined that luminescent zinc sulfide is not a dermal irritant or dermal sensitizer. The agency also reviewed two skin absorption studies in the petition. The agency determined that these studies showed an apparent low skin absorption of luminescent zinc sulfide, and that the petitioned use of luminescent zinc sulfide in facial makeup preparations is safe (Ref. 2). However, the agency also determined that these absorption studies were limited in their ability to measure skin absorption under all conditions of use. Therefore, new § 73.2995(c)(2) restricts the use of facial makeup preparations containing luminescent zinc sulfide to limited occasions (e.g., Halloween). In other words, under new § 73.2995(c)(2), facial makeup preparations containing luminescent zinc sulfide are not intended for regular or daily use. Furthermore, based on the luminescent zinc sulfide concentrations in facial makeup preparations stated in the petition, new § 73.2995(c)(1) limits the amount of luminescent zinc sulfide in facial makeup preparations to 10 percent by weight of the final product. The agency notes that luminescent zinc sulfide in nail polish would be bound in the polish once it dries on the nail, and hence, the skin contact of luminescent zinc sulfide would be minimal. Therefore, the agency concludes that a limit on the amount of luminescent zinc sulfide in nail polishes is not necessary for safety reasons.

Because the agency is approving the color additive only for limited applications, new § 73.2995(c) provides clear identification of the approved uses. The agency is limiting the approved uses of luminescent zinc sulfide to specific cosmetic product categories listed in § 720.4(c) (21 CFR 720.4). These product categories were proposed by the cosmetics industry in a petition to the agency to establish an FDA-administered Voluntary Cosmetic Registration Program (VCRP). FDA adopted these product categories in 1972 with the establishment of the VCRP (37 FR 7151, April 11, 1972). The agency has determined that referencing the relevant product categories in § 720.4(c) more clearly identifies the products in which use of luminescent zinc sulfide has been approved. Section 720.4(c) includes a category for nail polish (§ 720.4(c)(8)(v), Nail polish and enamel). Although § 720.4(c) does not include a specific category for facial makeup preparations for the specialty use that was proposed in the petition, it includes a category, other makeup preparations (§ 720.4(c)(7)(ix)), which includes this use. Referencing this cosmetic product category in the regulation effectively restricts it from being used in all other categories listed under § 720.4(c)(7), for which use of the color additive was not approved. The agency finds that references to the cosmetic product categories for the approved uses, together with the specific limitations in new § 73.2995(c)(1) and (c)(2) on the use of luminescent zinc sulfide in facial makeup preparations, will effectively define the uses that the agency has reviewed and determined to be safe.

The petition does not request use of luminescent zinc sulfide in the area of the eye, and therefore, contains no data to support the use of luminescent zinc sulfide applied to the area of the eye. Therefore, the agency is not including eye area use of luminescent zinc sulfide in new § 73.2995. However, because the probable use of facial makeup preparations would include use on children's faces at Halloween, the agency is concerned about the potential for the inappropriate use of these preparations in the area of the eye. Therefore, new § 73.2995(d)(2) requires the following statement on the product label: ''Do not use in the area of the eye.''

IV. Conclusion

Based on the data in the petition and other relevant material, FDA concludes that the proposed use of luminescent zinc sulfide as a color additive in nail polishes and specialized facial makeup preparations is safe, the additive will achieve its intended technical effect, and therefore, part 73 should be amended as set forth below. In addition, based upon the factors listed in 21 CFR 71.20(b), the agency concludes that certification of luminescent zinc sulfide is not necessary for the protection of the public health.

V. 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.

VI. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for CAP 7C0251 (62 FR 52136, October 6, 1997). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VII. Paperwork Reduction Act of 1995

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

VIII. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by September 7, 2000. 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 are to be submitted and are to 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**.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Murayama, Y., ''Luminous Paints,'' in S. Shionoya, and W. M. Yen, editors, *Phosphor Handbook*, pp. 651, 655–656, CRC Press, Boca Raton, FL, 1999.

2. Yourick, J. J., memorandum entitled ''Review of Toxicology Studies Contained in CAP7C0251, Use of Zinc Sulfide as a Color Additive in Cosmetics'' from the Cosmetics Toxicology Branch (HFS–128) to Aydin O–AE4rstan, Direct Additives Branch (HFS–215), Center for Food Safety and Applied Nutrition, FDA, March 14, 2000.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Foods, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR 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: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 73.2995 is added to subpart C to read as follows:

§ 73.2995 Luminescent zinc sulfide.

(a) *Identity*. The color additive luminescent zinc sulfide is zinc sulfide containing a copper activator. Following excitation by daylight or a suitable artificial light, luminescent zinc sulfide produces a yellow-green phosphorescence with a maximum at 530 nanometers.

(b) *Specifications*. Luminescent zinc sulfide shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Zinc sulfide, not less than 99.8 percent.
Copper, $100_{\pm}5$ parts per million.
Lead, not more than 20 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Cadmium, not more than 15 parts per million.

(c) *Uses and restrictions*. The color additive luminescent zinc sulfide may be safely used for coloring externally applied facial makeup preparations (included under § 720.4(c)(7)(ix) and (c)(8)(v) of this chapter) subject to the following restrictions:

(1) The amount of luminescent zinc sulfide in facial makeup preparations shall not exceed 10 percent by weight of the final product.

(2) Facial makeup preparations containing luminescent zinc sulfide are intended for use only on limited, infrequent occasions, e.g., Halloween, and not for regular or daily use.

(d) *Labeling requirements*. (1) The label of the color additive and any mixtures prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The label of a facial makeup preparation containing the color additive shall bear, in addition to other information required by the law, the following statement conspicuously displayed:

Do not use in the area of the eye.

(e) *Exemption from certification*. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: August 1, 2000.

Janice F. Oliver,

Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 00–19952 Filed 8–7–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 00F–0119]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Calcium Disodium EDTA and Disodium EDTA

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of calcium disodium EDTA (ethylenediaminetetraacetate) or disodium EDTA to promote color retention for all edible types of cooked, canned legumes. This action is in response to a petition filed by the National Food Processors Association.

DATES: This rule is effective August 8, 2000. Submit written objections and requests for a hearing by September 7, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mary E. LaVecchia, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3042.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of January 20, 2000 (65 FR