Optional Method of Compliance for TPE331 Series Engines Installed On Single-Engine Airplanes

(l) As an optional method of compliance to paragraph (h), (i), or (j) of this AD, for TPE331 series engines installed on single-engine airplanes, having an affected Woodward FCU assembly perform the following steps as necessary:

(1) Continue repetitive dimensional inspections of the fuel control drive, for wear or damage as specified in paragraph (g)(1) of this AD.

(2) Repair or replace the fuel pump or FCU assembly if the splines fail the dimensional inspection, with any serviceable fuel pump or FCU assembly.

Terminating Action

(m) Performing an FCU assembly replacement as specified in paragraph (h), (i), or (j) of this AD, is terminating action for the initial and repetitive inspections required by this AD.

Alternative Methods of Compliance

(n) The Manager, Los Angeles Aircraft Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(o) Information pertaining to operating recommendations for applicable engines after a fuel control drive failure is contained in OI 331–12R5 dated July 10, 2006, for multi-engine airplanes and in OI 331–18R3 dated July10, 2006, for single-engine airplanes.

Issued in Burlington, Massachusetts, on July 14, 2006.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E6–11540 Filed 7–19–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 1998C–0431] (formerly 98C–0431)

Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments

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 to provide for the safe use of mica-based pearlescent pigments as color additives in ingested drugs. After reviewing the objections, the agency has concluded that the objections do not raise issues of material fact that justify a hearing or otherwise provide a basis for revoking the amendment to the regulations. FDA is also establishing a new effective date for this color additive regulation, which was stayed by the filing of objections.

DATES: The final rule that published in the **Federal Register** of July 22, 2005 (the July 2005 final rule) (70 FR 42271), with an effective date of August 23, 2005, was stayed by the filing of objections as provided for under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)) as of August 22, 2005. This final rule is newly effective as of July 20, 2006.

FOR FURTHER INFORMATION CONTACT: Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1301.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the July 2005 final rule, FDA amended the color additive regulations to provide for the safe use of mica-based pearlescent pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color ingested drugs. The preamble to the final rule advised that objections to the final rule and requests for a hearing were due by August 22, 2005, and that the rule would be effective on August 23, 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 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 the grounds therefor, and requesting a public hearing upon such objections.'' FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing (21 CFR 12.24(b)(1)). (See also *Community Nutrition Institute* v. *Young*, 773 F.2d 1356, 1364 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986).)

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 for the use of mica-based pearlescent pigments to color ingested drugs, FDA received two submissions within the 30-day objection period. One submission objected to the use of pearlescent pigments in food. The submission did not request a hearing.

The second submission objected to the final rule on three grounds: (1) The subject pearlescent pigments would have iron contaminants, (2) these iron contaminants would cause stability issues for active ingredients in drugs, and (3) the use of iron-containing pearlescent pigments to color drugs would limit the availability of medications for those who are monitoring their iron intake. This submission requested a hearing on these issues.

III. Standards for Granting a Hearing

Specific criteria for determining whether to grant or deny a request for a hearing are set out in § 12.24(b). Under that regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (1) There is a genuine and substantial factual issue for resolution at a hearing (a hearing will not be granted on issues of policy or law); (2) the factual issue can be resolved by available and specifically identified reliable evidence (a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions); (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requester (a hearing will be denied if the data and information submitted are insufficient to justify the factual determination urged, even if accurate); (4) resolution of the factual issue in the

way sought by the person is adequate to justify the action requested (a hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the act or any regulation particularizing statutory standards (the proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved); and (6) the requirements in other applicable regulations, e.g., 21 CFR 10.20, 12.21, 12.22, 314.200, 514.200, and 601.7(a), and in the notice issuing the final regulation or the notice of opportunity for a hearing are met.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing'' (*Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), reh. denied, 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973)). An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test (*Georgia Pacific Corp.* v. *EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982)). If a hearing request fails to identify any factual evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute, and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies to administrative proceedings (see § 12.28).

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning whether a meaningful hearing might be held (*Pineapple Growers Association* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982)). Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing (see *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960)). FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information (see *United States* v. *Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971)). In other words, a hearing is justified only if the objections are made in good faith and if they ''draw in question in a material way the underpinnings of the regulation at issue'' (*Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977)). Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy (see *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958)).

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been raised and considered, a party is estopped from raising the same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles ''self-evidently'' ought to apply to an agency proceeding, the U.S. Court of Appeals for the District of Columbia Circuit wrote: ''The underlying concept is as simple as this: Justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.'' *Retail Clerks Union, Local 1401* v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972). (See also *Costle* v. *Pacific Legal Foundation*, supra at 215–220; *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.*, 404 F.2d 804 (D.C. Cir. 1968), *cert. denied*, 393 U.S. 1093 (1969).)

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact, and the evidence must be adequate to resolve the issue as requested and to justify the action requested.

One of the objections to the final rule on mica-based pearlescent pigments did not request a hearing. Therefore, FDA will rule upon the objection under §§ 12.24 through 12.28 (as cited in § 12.30(b)).

IV. Analysis of Objections

FDA addresses each of the two submissions in the following paragraphs, as well as the evidence and information filed in support of each, comparing each submission and the information submitted in support of it to the standards for ruling on objections and granting a hearing in § 12.24.

The first submission objected to the use of pearlescent pigments in food. This submission did not request a hearing. FDA notes that the final rule that is the subject of the objection provides for the safe use of mica-based pearlescent pigments to color ingested drugs, not foods. The objection to the use of pearlescent pigments in food is outside the scope of the July 2005 final rule. Therefore, FDA is denying this objection.

The second submission asserted that the subject pearlescent pigments would be contaminated with iron salts and that these contaminants would cause stability issues for active ingredients in drugs that could interfere with drug efficacy. The submission also asserted that the iron contaminants would increase exposure to iron. Furthermore, the submission was concerned that the use of iron-containing pearlescent pigments to color drugs would limit the availability of medications for those who are monitoring their iron intake. This submission requested a hearing on these issues.

Although this submission claimed that the subject pearlescent pigments would be contaminated with iron salts, the submission did not provide any factual information to support this claim. The July 2005 final rule was in response to a color additive petition (CAP 8C0257) that FDA had received from the manufacturer of the subject pearlescent pigments. During its review of the petition, FDA determined what specifications would be necessary to ensure the safe use of pearlescent pigments in ingested drugs and incorporated these specifications in the new § 73.1128 (21 CFR 73.1128). FDA also reviewed the results of analyses of several batches of pearlescent pigments and determined that they complied with the specifications in the new regulation. In the preamble to the final rule, FDA discussed the manufacturing process of the subject pearlescent pigments. FDA noted that the starting materials for these pigments included soluble iron salts and that the manufacturing incorporated a heating (calcination) step at temperatures up to 900 °C. FDA also noted that during calcination, the starting iron salts are converted into iron oxide.

The submission also asserted that the iron contaminants would destabilize active ingredients in drugs, which would affect drug efficacy. As noted previously in this document, the submission did not provide any factual information to support the claim that the subject pearlescent pigments would contain iron contaminants.

The third assertion in the submission was that the iron oxide in the subject pearlescent pigments is ''expected to limit availability of medications for the persons who must monitor iron intake.'' However, the submission did not provide any factual information to support this claim. FDA notes that, as

indicated in the preamble to the July 2005 final rule, the bioavailability of these pigments and/or their individual components when ingested is expected to be low.

This submission did not provide any factual information to modify FDA's conclusion that the subject pearlescent pigments present no toxic potential when ingested at levels estimated by the agency, based on their proposed use in coloring ingested drugs. Namely, this submission did not provide specifically identified reliable evidence that can lead to resolution of a factual issue in dispute (§ 12.24(b)(2)). A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions (§ 12.24(b)(2)). Therefore, FDA is denying this objection.

V. Summary and Conclusions

The agency is denying the objections to the final rule in the two submissions received on the following bases. The objection to the use of pearlescent pigments in food is outside the scope of the July 2005 final rule, which amended the color additive regulations to provide for the safe use of mica-based pearlescent pigments to color ingested drugs. The objections in the second submission that the subject pearlescent pigments would contain iron contaminants, that the iron contaminants would cause stability issues for active ingredients in drugs, and that the use of the pigments to color ingested drugs will limit availability of medications for the persons who must monitor their iron intake, are not supported by any factual information.

The filing of the objections served to stay automatically the effectiveness of § 73.1128. Section 701(e)(2) of the act states: ''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 stipulates 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 July 20, 2006 for this regulation listing mica-based pearlescent pigments prepared from synthetic iron oxide, mica, and titanium dioxide to color ingested drugs. As announced in the July 22, 2005, final rule, the previous effective date of the regulation was August 23, 2005.

Therefore, under sections 701 and 721 of the act, notice is given that the objections filed in response to the July 2005 final rule do not form the basis for further stay of this final rule or require amendment of the regulations. Accordingly, the stay of § 73.1128 that FDA is announcing in this document is removed effective July 20, 2006.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e) and under authority delegated to the Commissioner of Food and Drugs (section 1410.10 of the FDA Staff Manual Guide), notice is given that objections and a request for a hearing were filed in response to the July 22, 2005, final rule. Notice is also given that the agency is denying these objections. Accordingly, the amendments issued thereby are effective July 20, 2006.

Dated: July 14, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–11536 Filed 7–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Parts 1926 and 1928

[Docket No. S–270–A]

RIN 1218–AC15

Roll-Over Protective Structures

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Final rule; corrections and technical amendments.

SUMMARY: On December 29, 2005, OSHA published a direct final rule in the **Federal Register** reinstating its original construction and agriculture standards that regulate the testing of roll-over protective structures (''ROPS'') used to protect employees who operate wheel-type tractors. OSHA received one comment to the direct final rule; this comment recommended a number of clarifications to the original ROPS standards published in the direct final rule. In the present notice, the Agency is making corrections and technical amendments to the ROPS standards in response to this comment, as a result of editorial errors found in the ROPS standards published in the direct final rule, and to improve consistency among the figures generated for these standards. The Agency finds that these corrections and technical amendments do not change the substantive requirements of the ROPS standards.

DATES: The corrections and technical amendments specified by this rulemaking become effective on July 20, 2006.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Kevin Ropp, OSHA Office of Communications, Room N–3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–1999.

General and technical information: Matthew Chibbaro, Acting Director, Office of Safety Systems, Directorate of Standards and Guidance, Occupational Safety and Health Administration, U.S. Department of Labor, Room N–3609, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693–2255.

SUPPLEMENTARY INFORMATION: On December 29, 2005, OSHA published a direct final rule in the **Federal Register** reinstating its original construction and agriculture standards that regulate the testing of roll-over protective structures (''ROPS'') used to protect employees who operate wheel-type tractors (see 70 FR 76979). The Agency received only one public comment (Ex. 3–1) on the direct final rule, which it determined was not a significant adverse comment. The commenter recommended several clarifications to the ROPS standards published in the direct final rule.

The table below describes the clarifications recommended by the commenter who responded to the direct final rule, and OSHA's response to these recommendations. This response provides the Agency's rationale for accepting a recommendation or excluding it from further consideration. Accordingly, OSHA is making a number of corrections and technical amendments to the ROPS standards for construction (§ 1926.1002) and agriculture (§§ 1928.52 and 1928.53) based on the commenter's recommendations.