

for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the

FAA Flight Standards Certificate Holding District Office.

Related Information

(j) The subject of this AD is addressed in French airworthiness directives F-2005-111 R1, dated December 21, 2005, and F-2000-115-304 R5, dated July 6, 2005.

Material Incorporated by Reference

(k) You must use the documents identified in Table 2 of this AD, as applicable, to perform the actions that are required by this AD, unless the AD specifies otherwise.

TABLE 2.—DOCUMENTS INCORPORATED BY REFERENCE

Airbus Service Bulletin	Revision	Date
A300-22-6050	Original	October 8, 2004.
A300-22A0115	02, including Appendix 01	March 7, 2000.
A300-22A6042	01, including Appendix 01	March 7, 2000.
A310-22-2058	Original	April 6, 2005.
A310-22A2053	01, including Appendix 01	March 7, 2000.

(1) The Director of the Federal Register approved the incorporation by reference of the documents identified in Table 3 of this

AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

TABLE 3.—NEW DOCUMENTS INCORPORATED BY REFERENCE

Airbus Service Bulletin	Revision	Date
A300-22-6050	Original	October 8, 2004.
A310-22-2058	Original	April 6, 2005.

(2) On December 20, 2000 (65 FR 68876, November 15, 2000), the Director of the Federal Register approved the incorporation

by reference of the documents identified in Table 4 of this AD.

TABLE 4.—DOCUMENTS PREVIOUSLY INCORPORATED BY REFERENCE

Airbus Service Bulletin	Revision	Date
A300-22A0115	02, including Appendix 01	March 7, 2000.
A300-22A6042	01, including Appendix 01	March 7, 2000.
A310-22A2053	01, including Appendix 01	March 7, 2000.

(3) Contact Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Room PL-401, Nassif Building, Washington, DC; on the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on July 7, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6-11414 Filed 7-19-06; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2006-23706; Directorate Identifier 2006-NE-03-AD; Amendment 39-14688; AD 2006-15-08]

RIN 2120-AA64

Airworthiness Directives; Honeywell International Inc. TPE331 Series Turboprop Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Honeywell International Inc. TPE331 series turboprop engines with certain part numbers of Woodward fuel control unit (FCU) assemblies installed. This AD requires initial and repetitive

dimensional inspections of the fuel control drive, for wear or damage. This AD results from reports of loss of the fuel control drive, leading to engine overspeed, overtorque, overtemperature, uncontained rotor failure, and asymmetric thrust in multi-engine airplanes. We are issuing this AD to prevent destructive overspeed that could result in uncontained rotor failure, and damage to the airplane.

DATES: This AD becomes effective August 24, 2006.

ADDRESSES: You can get the service information identified in this AD from Honeywell Engines, Systems & Services, Technical Data Distribution, M/S 2101-201, P.O. Box 52170, Phoenix, AZ 85072-2170; telephone: (602) 365-2493 (General Aviation); (602) 365-5535 (Commercial); fax: (602) 365-5577 (General Aviation and Commercial).

You may examine the AD docket on the Internet at <http://dms.dot.gov> or in Room PL-401 on the plaza level of the

Nassif Building, 400 Seventh Street, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT:

Joseph Costa, Aerospace Engineer, Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate, 3960 Paramount Blvd., Lakewood, CA 90712-4137; telephone (562) 627-5246; fax (562) 627-5210.

SUPPLEMENTARY INFORMATION: The FAA proposed to amend 14 CFR part 39 with a proposed airworthiness directive (AD). The proposed AD applies to Honeywell International Inc. TPE331 series turboprop engines with certain part numbers of Woodward FCU assemblies installed. We published the proposed AD in the **Federal Register** on March 8, 2006 (71 FR 11546). That action proposed to require initial and repetitive dimensional inspections of the drive splines between the fuel pump and fuel control governor, for wear or damage.

Examining the AD Docket

You may examine the docket that contains the AD, any comments received, and any final disposition in person at the Docket Management Facility Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647-5227) is located on the plaza level of the Department of Transportation Nassif Building at the street address stated in **ADDRESSES**. Comments will be available in the AD docket shortly after the DMS receives them.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Clarification of Discussion Paragraph

Honeywell International Inc. points out that in the discussion section of the Notice of Proposed Rulemaking we stated that installation of an improved fuel control will eliminate the overspeed condition by better accommodating a drive spline failure. Honeywell suggests that we change the discussion to state that replacing an affected fuel control assembly with an improved fuel control assembly will only reduce the possibility of an overspeed, rather than eliminate it altogether. We agree that Honeywell's suggestion has some logic from a risk management perspective. We recognize that the improved fuel control may not eliminate the possibility of a drive spline failure or the resulting engine overspeed condition, but we intend that it will eliminate a destructive overspeed

due to this spline failure. We have, however, changed paragraph (d) of the final rule (the statement of the unsafe condition) to clarify that we expect that the AD will prevent destructive overspeed that could result in uncontained rotor failure, and damage to the airplane.

Suggestion to Specifically Reference Pump Splines

Honeywell International Inc. also suggests that we add the words "or pump" after "fuel control" in both paragraphs (f)(2) and (g)(2) of the proposed rule. Honeywell points out that the proposed inspections also include the fuel pump spline as well as the fuel control splines. We agree that the required inspections include the fuel pump spline and that if the fuel pump spline fails inspection, the fuel pump would require repair or replacement. Therefore, we have added references to the fuel pump in paragraphs (f), (g), and (l) of the final rule. We have also split the repair and replace requirement in paragraphs (f) and (g) into one sub-paragraph for the fuel pump, (f)(2) and (g)(2), and one for the fuel control assembly, (f)(3) and (g)(3), which we now refer to as the fuel control unit (FCU) assembly. We made these changes to keep clear that the replacement requirements of the AD call for "modified" FCU assemblies for multi-engine airplanes. Fuel pump assemblies whose splines fail dimensional inspection may be replaced with serviceable fuel pump assemblies.

Request To Add the Word "Governor"

Honeywell International Inc. also requests that we add the word "governor" to describe the splined driveshafts between the fuel pump and the FCU. Honeywell points out that the proposal could be read so as not to include a required inspection of the quill shaft internal to the fuel control. We agree, and have added a definition of the term "fuel control drive" to paragraph (k) of the final rule that includes the change of "fuel control" to "fuel control governor."

Claim That Destructive Overspeed Is Still Possible

An FAA-approved repair station, Turbine Standard, Ltd, claims that destructive engine overspeed is really only possible on the ground with the prop "on the start locks" and will continue to be possible with the new modified fuel control assembly. The commenter states that according to Honeywell's Operating Information Letters OI331-12R4, dated March 29, 2006, and OI331-18R2, dated March 29,

2006, the possibility of uncontained separation of the engine's high speed rotating components still exists, at certain conditions. Furthermore, the commenter appears to question the need for this AD by pointing out that wear of the FCU and fuel pump drive can be adequately managed by following the recommended maintenance program for the engine and that any FCUs that showed heavy spline wear were addressed by a previous AD, AD 94-26-07.

We do not agree. The proposed rule and this AD address a continuing problem that has caused 51 known incidents over the past 30 years. We believe that the fuel pump and fuel control spline failures represent a serious unsafe condition that requires mandatory inspections and replacement of existing fuel control designs to warrant AD action rather than reliance on recommended maintenance practices. Even after issuing AD 94-26-07, we continue to receive reports of fuel control drive failures, overspeed, and destructive overspeed events. With a modified FCU installed, AD 94-26-07 will no longer apply.

Whether destructive overspeeds will continue to be possible with the new modified fuel control assembly, we recognize that this failure condition is rare and only exists under certain high-temperature and high-altitude ground start conditions, with certain older design engines while the prop is "on the locks". When this set of rare conditions is coupled with the fuel control drive low failure rate, a destructive overspeed is improbable. We consider the modified FCU assembly to be safe.

Claim That Asymmetric Thrust Would be More Prevalent

Turbine Standard, Ltd also claims that the modified fuel control assembly installed on an engine on a multi-engine airplane would actually make asymmetric thrust more likely in the event of a fuel pump or fuel control drive spline failure. The commenter explains that after the failure of a fuel control drive on a modified fuel control assembly, the modified fuel control would deliver only 180 PPH of fuel flow, which is below flight idle fuel flow. Since fuel flows for take off thrust are normally very high and the failure mode of an unmodified fuel control unit typically delivers more fuel flow, the commenter concludes that the aircrew would be in a worse situation with a modified fuel control after suffering drive spline failure than with a non-modified fuel control.

We do not agree. While it is true that the fuel flow after drive spline failure

with a modified fuel control unit may result in a more pronounced asymmetric thrust condition at takeoff, we believe that after considering all ground and flight conditions, the modified FCU assembly is much safer than the applicable FCU assembly on the multi-engine aircraft. In addition, with a modified fuel control, the failure mode would produce a clearly evident decrease in thrust that a trained aircrew can easily recognize and safely handle, even on takeoff.

AD Does Not Address Recommendations to the Pilot on Negative Torque Sensing

Turbine Standard, Ltd also claims that the proposed AD does not address recommendations to the pilot if the engine starts to experience "negative torque sensing" during flight. The commenter reasons that after the failure of a fuel control drive spline, the modified fuel control assembly will deliver 180 PPH of fuel flow, which may be below flight idle fuel flow, and the engine may experience negative torque sensing (NTS). In addition, "negative torque sensing" at higher than normal engine speeds for long periods, might damage the propeller.

We do not agree that the AD needs to include mandatory instructions to the aircrew concerning NTS. The commenter is correct that during flight with the modified FCU assembly installed, the engine may experience NTS after failure of a fuel control drive. We believe that having the pilot shut down the engine as soon as possible after drive spline failure by recognizing an unresponsive power lever, consistent with the safe operation of the airplane, is the best action. We have changed paragraph (o) of the final rule to reference Honeywell's operating information letters.

Claim That the Modified FCU Assembly Is Not Necessary

Lastly, Turbine Standard, Ltd claims that the modified FCU assembly is not necessary because of the propeller governor response to an engine overspeed, if the airplane is equipped with torque and temperature limiting (TTL) devices. The commenter believes that fuel bypassing the TTL devices and the propeller governor should maintain engine speed at its set point after a fuel control drive failure.

We do not agree. Engine testing shows that the TTL devices cannot bypass sufficient fuel and the propeller governor cannot maintain speed consistently enough to ensure a safe operation of the TPE331 engine. In addition, since the TTL devices are

optional devices for some aircraft, the TTL's marginal and temporary benefit is not a safe alternative.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

We estimate this AD will affect 3,250 engines installed on airplanes of U.S. registry. We also estimate it will take about one work-hour per engine to replace the FCU assembly during a normal scheduled overhaul. We also estimate it will take about three work-hours to perform a dimensional inspection of the fuel control drive. The average labor rate is \$65 per work-hour. A replacement FCU assembly will cost about \$9,700 per engine. We estimate that on each engine, one FCU assembly inspection will be performed, and each engine will have the FCU assembly replaced. Based on these figures, we estimate the total cost of the AD to U.S. operators to be \$32,370,000.

The Agency is committed to updating the aviation community of expected costs associated with the MU-2B series airplane safety evaluation conducted in 2005. As a result of that commitment, the accumulating expected costs of all ADs related to the MU-2B series airplane safety evaluation may be found at the following Web site: http://www.faa.gov/aircraft/air_cert/design_approvals/small_airplanes/cos/mu2_foia_reading_library/.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on

products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

- (1) Is not a "significant regulatory action" under Executive Order 12866;
- (2) Is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and
- (3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a summary of the costs to comply with this AD and placed it in the AD Docket. You may get a copy of this summary at the address listed under **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2006-15-08 Honeywell International Inc. (formerly AlliedSignal Inc., Garrett Engine Division; Garrett Turbine Engine Company; and AiResearch Manufacturing Company of Arizona): Amendment 39-14688; Docket No. FAA-2006-23706; Directorate Identifier 2006-NE-03-AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective August 24, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Honeywell International Inc. TPE331-1, -2, -2UA, -3U,

-3UW, -5, -5A, -5AB, -5B, -6, -6A, -10, -10AV, -10GP, -10GT, -10P, -10R, -10T, -10U, -10UA, -10UF, -10UG, -10UGR,

-10UR, -11U, -12JR, -12UA, -12UAR, and -12UHR turboprop engines with the part numbers (P/Ns) of Woodward fuel control

unit (FCU) assemblies listed in this AD, installed. These engines are installed on, but not limited to, the following airplanes:

Manufacturer	Model
AERO PLANES, LLC (formerly McKinnon Enterprises)	G-21G.
ALLIED AG CAT PRODUCTIONS (formerly Schweizer)	G-164 Series.
AYRES	S-2R Series.
BRITISH AEROSPACE LTD (formerly Jetstream)	3101 and 3201 Series, and HP.137 JETSTREAM MK.1.
CONSTRUCCIONES AERONAUTICAS, S.A. (CASA)	C-212 Series.
DEHAVILLAND	DH104 Series 7AXC (DOVE).
DORNIER	228 Series.
FAIRCHILD	SA226 and SA227 Series (SWEARINGEN MERLIN and METRO SERIES).
GRUMMAN AMERICAN	G-164 Series.
MITSUBISHI	MU-2B Series (MU-2 Series).
PILATUS	PC-6 Series (FAIRCHILD PORTER and PEACEMAKER).
POLSKIE ZAKLADY LOTNICZE SPOLKA (formerly Wytownia Sprzetu Komunikacyjnego).	PZL M18, PZL M18A, PZL M18B.
PROP-JETS, INC.	400.
RAYTHEON AIRCRAFT (formerly Beech)	C45G, TC-45G, C-45H, TC-45H, TC-45J, G18S, E18S-9700, D18S, D18C, H18, RC-45J, JRB-6, UC-45J, 3N, 3NM, 3TM, B100, C90 and E90.
SHORTS BROTHERS and HARLAND, LTD.	SC7 (SKYVAN) Series.
THRUSH (ROCKWELL COMMANDER)	S-2R.
TWIN COMMANDER (JETPROP COMMANDER)	680, 690 and 695 Series.

Unsafe Condition

(d) This AD results from reports of loss of the fuel control drive, leading to engine overspeed, overtorque, overtemperature, uncontained rotor failure, and asymmetric thrust in multi-engine airplanes. We are issuing this AD to prevent destructive overspeed that could result in uncontained rotor failure, and damage to the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

Initial Inspection of Engines With Affected FCU Assemblies

(f) At the next scheduled inspection of the fuel control drive, but within 1,000 hours-in-service after the effective date of this AD:

(1) Perform an initial dimensional inspection of the fuel control drive for wear or damage. Information on spline inspection can be found in Section 72-00-00 of the applicable maintenance manuals.

(2) Repair or replace the fuel pump, if the spline fails the dimensional inspection, with any serviceable fuel pump.

(3) Repair or replace the FCU assembly, if the splines fail the dimensional inspection, with a serviceable modified FCU assembly.

Repetitive Inspections of Engines With Affected FCU Assemblies

(g) Thereafter, within 1,000 hours since-last-inspection:

(1) Perform repetitive dimensional inspections of the fuel control drive, for wear or damage. Information on spline inspection can be found in Section 72-00-00 of the applicable maintenance manuals.

(2) Repair or replace the fuel pump, if the spline fails the dimensional inspection, with any serviceable fuel pump.

(3) Repair or replace the FCU assembly if the splines fail the dimensional inspection, with a serviceable modified FCU assembly.

TPE331-1, -2, and -2UA Series Engines

(h) For TPE331-1, -2, and -2UA series engines, replace Woodward FCU assemblies, P/Ns 869199-13/ -20/ -21/ -22/ -23/ -24/ -25/ -26/ -27/ -28/ -29/ -31/ -32/ -33/ -34, and -35, with a serviceable, modified FCU assembly the next time the FCU assembly is removed for cause that requires return, or when the FCU assembly requires overhaul, but not later than December 31, 2012. Information on replacement FCU assembly P/Ns, configuration management, rework, and replacement information, can be found in Honeywell Alert Service Bulletin (ASB) No. TPE331-A73-0271, Revision 1, dated January 25, 2006.

TPE331-3U, -3UW, -5, -5A, -5AB, -5B, -6, -6A, -10AV, -10GP, -10GT, -10P, and -10T Series Engines

(i) For TPE331-3U, -3UW, -5, -5A, -5AB, -5B, -6, -6A, -10AV, -10GP, -10GT, -10P, and -10T series engines, replace Woodward FCU assemblies, P/Ns 893561-7/ -8/ -9/ -10/ -11/ -14/ -15/ -16/ -20/ -26/ -27, and -29, and P/Ns 897770-1/ -3/ -7/ -9/ -10/ -11/ -12/ -14 / -15/ -16/ -25/ -26, and -28, with a serviceable, modified FCU assembly the next time the FCU assembly is removed for cause that requires return, or when the FCU assembly requires overhaul, but not later than December 31, 2012. Information on replacement FCU assembly P/Ns, configuration management, rework, and replacement information, can be found in Honeywell ASB No. TPE331-A73-0262, Revision 2, dated June 17, 2005.

TPE331-10, -10R, -10U, -10UA, -10UF, -10UG, -10UGR, -10UR, -11U, -12JR, -12UA, -12UAR, and -12UHR Series Engines

(j) For TPE331-10, -10R, -10U, -10UA, -10UF, -10UG, -10UGR, -10UR, -11U, -12JR, -12UA, -12UAR, and -12UHR series engines, replace Woodward FCU assemblies, P/Ns 897375-2/ -3/ -4/ -5/ -8/ -9/ -10/ -11/ -12/ -13/ -14/ -15/ -16/ -17/ -19/ -21/ -24/ -25/ -26, and -27, and P/Ns 897780-1/ -2/ -3/ -4/ -5/ -6/ -7/ -8/ -9/ -10/ -11/ -14/ -15/ -16/ -17/ -18/ -19/ -20/ -21/ -22/ -23/ -24/ -25/ -26/ -27/ -30/ -32/ -34/ -36/ -37, and -38, and P/Ns 893561-17/ -18, and -19, with a serviceable, modified FCU assembly the next time the FCU assembly is removed for cause that requires return, or when the FCU assembly requires overhaul, but not later than December 31, 2012. Information on replacement FCU assembly P/Ns, configuration management, rework, and replacement information, can be found in Honeywell ASB No. TPE331-A73-0254, Revision 2, dated June 17, 2005.

Definitions

(k) For the purposes of this AD:

(1) A “serviceable, modified FCU assembly” for engines affected by paragraph (h), (i), or (j) of this AD, is an FCU assembly with a P/N not listed in this AD.

(2) The “fuel control drive” is a series of mating splines located between the fuel pump and fuel control governor, consisting of the following four drive splines: The fuel pump internal spline, the fuel control external “quill shaft” spline, and the stub shaft internal and external splines.

(3) A “removal for cause that requires return”, for engines affected by paragraph (h), (i), or (j) of this AD, is an FCU assembly that has displayed an unserviceable or unacceptable operating condition requiring the FCU to be removed from service and sent to a repair or overhaul shop.

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 July 10, 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