PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

1. The authority citation for part 72 continues to read as follows:


Section 72.44(g) also under issued secs. 142(b) and 148(c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10166(c),(d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)).

Subpart J also issued under secs. 2(2), 2(18), 117(a), 141(b), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(b)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

2. In §72.214, Certificate of Compliance 1032 is added to read as follows:

§72.214 List of approved spent fuel storage casks.

Certificate Number: 1032.

Initial Certificate Effective Date: June 13, 2011.

SAR Submitted by: Holtec International, Inc.

SAR Title: Safety Analysis Report on the HI–STORM FW System.

Docket Number: 72–1032.

Certificate Expiration Date: June 13, 2031.

Model Numbers: MPC–37, MPC–89.

Dated at Rockville, Maryland, this 8th day of February 2011.
safety equivalent to the current regulations for reference stall speeds, stall warning, stall characteristics, and miscellaneous other minimum reference speeds.

**Discussion of Comments**

Notice of proposed special conditions No. 25–10–03–SC for Gulfstream GVI airplanes was published in the Federal Register on December 23, 2010 (75 FR 80735). One supportive comment was received.

**Applicability**

As discussed above, these special conditions are applicable to the high incidence protection system on the GVI. Should Gulfstream apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, these special conditions would apply to that model as well.

**Conclusion**

This action affects only certain novel or unusual design features of the GVI. It is not a rule of general applicability.

**List of Subjects in 14 CFR Part 25**

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

**The Special Conditions**

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Gulfstream GVI airplanes.

1. **Definitions.** For terminology that does not appear in the regulations, the following definitions apply to these special conditions:

   (a) **Electronic Flight Control System (EFCS)**—The electronic and software command and control elements of the flight control system.

   (b) **High Incidence Protection Function**—An airplane level function that automatically limits the maximum angle of attack that can be attained to a value below that at which an aerodynamic stall would occur.

   (c) **Alpha-Limit**—The maximum angle of attack at which the airplane stabilizes with the high incidence protection function operating and the longitudinal control held on its aft stop.

   (d) **Vmin**—The minimum stabilized flight speed in calibrated airspeed obtained when the airplane is decelerated at an entry rate not exceeding 1 knot/sec until the longitudinal pilot control is on the aft stop with the high incidence protection function operating.

   (e) **Vmin1g**—Vmin corrected to 1g conditions. The minimum calibrated airspeed at which the airplane can develop a lift force normal to the flight path and equal to its weight when at an angle of attack not greater than that determined for Vmin.

2. **Capability and Reliability of the High Incidence Protection System**—In lieu of §§ 25.103, 25.145, 25.201, 25.203, 25.207 and 25.1323, the following special conditions are issued for capability and reliability requirements:

   (a) It must not be possible during pilot-induced maneuvers to encounter a stall, and handling characteristics must be acceptable as required by paragraphs 5 and 6 of this special condition.

   (b) The airplane must be protected against stalling due to the effects of environmental conditions such as windshear and gusts at low speeds as required by paragraph 7 of this special condition.

   (c) The ability of the high incidence protection function to accommodate any reduction in stalling angle of attack resulting from flight in the atmospheric icing conditions of 14 CFR part 25, appendix C, must be verified.

   (d) The reliability of the high incidence protection function and the effects of failures must be acceptable in accordance with § 25.1309.

   (e) The high incidence protection function must not impede maneuvering for pitch angles up to the maximum required for normal maneuvering including an all-engines operating takeoff plus a suitable margin to allow for satisfactory speed control.

3. **Minimum Steady Flight Speed and Reference Stall Speed**—In lieu of the requirements of § 25.103, the following special condition is issued:

   (a) **Vmin**—The minimum steady flight speed, for the airplane configuration under consideration and with the high incidence protection function operating, is the final stabilized calibrated airspeed obtained when the airplane is decelerated at an entry rate not exceeding 1 knot per second until the longitudinal pilot control is on its stop.

   (b) The minimum steady flight speed, Vmin, must be determined with:

   1. The high incidence protection function operating normally.

   2. Idle thrust.

   3. All combinations of flap settings and landing gear positions.

   4. The weight used when VSR is being used as a factor to determine compliance with a required performance standard.

   5. The most unfavorable center of gravity allowable.

   (6) The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 VSR and not greater than 1.3 VSR.

   (7) The settings of the high incidence protection function, stall warning system, and stall identification system (if applicable) set at the low angle of attack tolerance limit, unless the production tolerances are acceptably small so as to produce insignificant changes in performance determinations.

   (c) **Vmin1g**—Vmin corrected to 1g conditions, which is the minimum calibrated airspeed at which the airplane can develop a lift force normal to the flight path and equal to its weight when at an angle of attack not greater than that determined for Vmin. Vmin1g is defined as follows:

   \[
   V\text{min1g} = \frac{V\text{min}}{\sqrt{n_{\text{SW}}}}
   \]

   Where:

   \[\text{n_{SW}}\] = load factor normal to the flight path at \[V\text{min}\].

   (d) The reference stall speed, \[V\text{SR}\], is a calibrated airspeed selected by the applicant. \[V\text{SR}\] may not be less than a 1g stall speed. \[V\text{SR}\] is expressed as:
\[ V_{SR} \geq V_s 1g = \frac{V_{CL,\text{MAX}}}{\sqrt{n_{zw}}} \]

where:

- \( V_{CL,\text{MAX}} \) is the calibrated airspeed obtained when the load factor-corrected \( qS \) lift coefficient is first a maximum during the maneuver prescribed in paragraph 3(e)(7) of this special condition.

\[ n_{zw}W = \text{Load factor normal to the flight path at } V_{CL,\text{MAX}} \]

\[ W = \text{Airplane gross weight;} \]

\[ S = \text{Aerodynamic reference wing area; and} \]

\[ q = \text{Dynamic pressure}. \]

(e) \( V_{SR} \) must be determined with the following conditions:

1. Engines idling, or, if that resultant thrust causes an appreciable decrease in stall speed, not more than zero thrust at the stall speed.
2. The airplane in other respects (such as flaps and landing gear) in the condition existing in the test or performance standard in which \( V_{SR} \) is being used.
3. The weight used when \( V_{SR} \) is being used as a factor to determine compliance with a required performance standard.
4. The center of gravity position that results in the highest value of reference stall speed.
5. The airplane trimmed for straight flight at a speed selected by the applicant, but not less than 1.13 \( V_{SR} \) and not greater than 1.3 \( V_{SR} \).

(f) The flight characteristics at the angle of attack corresponding to \( V_{SR} \) must be suitable in the traditional sense at forward and aft center of gravity in straight and turning flight at IDLE power.

(g) If \( V_{SR} \) is chosen equal to \( V_{MIN,1g} \), an equivalent safety finding to the intent of § 25.103 may be considered to have been met. The applicant may choose \( V_{SR} \) to be less than \( V_{MIN,1g} \) but not less than \( V_{S1g} \) if compensating factors are provided to ensure safe characteristics.

4. Stall Warning

(a) Normal Operation—If the conditions of paragraph 2 of this special condition are satisfied, a level of safety equivalent to that intended by § 25.207, Stall warning, will have been met.

(b) Failure Cases—Following failures of the high incidence protection function not shown to be extremely improbable, if the function no longer satisfies paragraphs 2(a), 2(b), and 2(c) of this special condition, stall warning must be provided in accordance with § 25.207. The stall warning should prevent inadvertent stall in the following conditions:

1. Power off straight stall approaches to a speed 5 percent below the warning onset.
2. Turning flight stall approaches with at least 1.5g load factor normal to the flight path at an entry rate of at least 2 knots per second when recovery is initiated not less than one second after the warning onset.

5. High Incidence Handling Demonstrations—In lieu of the requirements of § 25.201, the following special condition are issued:

(a) Maneuvers to the limit of the longitudinal control, in the nose up direction, must be demonstrated in straight flight and in 30 degree banked turns under the following conditions:

1. The high incidence protection function operating normally.
2. Power off.
3. At a power level necessary to maintain level flight at 1.5 \( V_{SR1} \), where \( V_{SR1} \) is the reference stall speed with the flaps in the approach position, the landing gear retracted, and with the aircraft at its maximum landing weight. The flap position to be used to determine this power setting is that position in which the stall speed, \( V_{SR1} \), does not exceed 110% of the stall speed, \( V_{SR0} \), with the flaps in the most extended landing position.

(b) In each condition required by paragraph (a) of this section, it must be possible to meet the applicable requirements of § 25.203 defined in paragraph 6 of this special condition with:

1. Flaps, landing gear, and deceleration devices in any likely combination of positions not prohibited.
2. Deceleration devices include spoilers and other drag devices when used as air brakes, and thrust reversers. High incidence maneuver demonstrations with deceleration devices deployed should be carried out with power off except where power is normally applied during operations (e.g., use of extended airbrakes during landing).

3. Representative weights within the range for which certification is requested.
4. The most adverse center of gravity.
5. The airplane trimmed for straight flight at the speed prescribed in paragraph 3(e)(7) of this special condition.

(c) The following procedures must be used to show compliance with § 25.203 as amended by paragraph 6 of this special condition:

6. The settings of the high incidence protection function, stall warning system, and stall identification system (if applicable) set at the high angle of attack tolerance limit, unless the production tolerances are acceptably small so as to produce insignificant changes in performance determinations.
(1) Starting at a speed sufficiently above the minimum steady flight speed to ensure that a steady rate of speed reduction can be established, apply the longitudinal control so that the speed reduction does not exceed one knot per second until the control reaches the stop.

(2) The longitudinal control must be maintained at the stop until the airplane has reached a stabilized flight condition and then recovered by normal recovery techniques.

(3) The requirements for turning flight maneuver demonstrations must also be met with accelerated rates of entry to the incidence limit, up to the maximum rate achievable.

6. Characteristics in High Incidence Maneuvers — In lieu of the requirements of §25.203, the following special condition is issued:

(a) Throughout maneuvers with a rate of deceleration of not more than 1 knot per second, both in straight flight and in 30 degree banked turns, the airplane’s characteristics must be as follows:

(1) No abnormal airplane nose-up pitching.

(2) No uncommanded nose-down pitching (which is indicative of stall). However, reasonable attitude changes associated with stabilizing the incidence at alpha limit as the longitudinal control reaches the stop is acceptable. Any reduction of pitch attitude associated with stabilizing the incidence at the alpha limit should be achieved smoothly and at a low pitch rate, so it is not likely to be mistaken for natural stall identification.

(3) No uncommanded lateral or directional motion, and the pilot must retain good lateral and directional control by conventional use of the cockpit controls throughout the maneuver.

(4) The airplane must not exhibit buffeting of a magnitude or severity that would act as a deterrent to completing the maneuver specified in §25.201(a) as amended by this special condition.

(b) In maneuvers with increased rates of deceleration, some degradation of characteristics associated with a transient excursion beyond the stabilized alpha-limit is acceptable. However, the airplane must not exhibit dangerous characteristics or characteristics that would deter the pilot from holding the longitudinal control on the aft stop for a period of time appropriate to the maneuvers.

(c) It must always be possible to reduce incidence by conventional use of the longitudinal control.

(d) The rate at which the airplane can be maneuvered from trim speeds associated with scheduled operating speeds, such as $V_{MO}$ and $V_{SR1}$ up to alpha-limit, should not be unduly damped or significantly slower than can be achieved on conventionally controlled transport airplanes.

7. Atmospheric Disturbances — Operation of the high incidence protection function must not adversely affect aircraft control during expected levels of atmospheric disturbances, nor impede the application of recovery procedures in case of windshear. Simulator tests and analysis may be used to evaluate such conditions, but must be validated by limited flight testing to confirm handling qualities at critical loading conditions.

8. Longitudinal Control — In lieu of the requirements of §25.145(a), a)(1) and (b)(6), the following special conditions are issued:

(a) It must be possible, at any point between the trim speed prescribed in §25.103(b)(6) as amended by this special condition and $V_{min}$, to pitch the nose downward so that the acceleration to this selected trim speed is prompt.

(b) With the landing gear extended, no change in trim control, or exertion of more than 50 pounds control force (representative of the maximum short-term force that can be applied readily by one hand) may be required for the following maneuver: With power off, flaps extended and the airplane trimmed at 1.3 $V_{SR1}$, obtain and maintain airspeeds between $V_{min}$ and either 1.6 $V_{SR1}$ or $V_{Fe}$, whichever is lower.

9. Airspeed Indicating System — In lieu of §25.1323(c)(1) and (c)(2), the following special conditions are issued:

(a) $V_{MO}$ to $V_{min}$ with the flaps retracted; and

(b) $V_{min}$ to $V_{Fe}$ with flaps in the landing position.

Issued in Renton, Washington, on March 18, 2011.

KC Yanamura,
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 529


New Animal Drugs; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The supplemental ANADA provides for use of oxytetracycline hydrochloride soluble powder for control of American and European foulbrood in honey bees and for skeletal marking of finfish fry and fingerlings.

DATES: This rule is effective March 28, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, filed a supplement to ANADA 200–026 that provides for use of PENNOX 343 (oxytetracycline HCl) Soluble Powder for control of American and European foulbrood in honey bees and for skeletal marking of finfish fry and fingerlings by immersion. The supplemental ANADA is approved as of December 6, 2010, and the regulations in 21 CFR 520.1660d and 529.1660 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Parts 520 and 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21