

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Proposed Amendment**

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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 Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

**Airbus:** Docket No. FAA-2005-22524; Directorate Identifier 2005-NM-135-AD.

**Comments Due Date**

(a) The FAA must receive comments on this AD action by October 27, 2005.

**Affected ADs**

(b) None.

**Applicability**

(c) This AD applies to Airbus Model A330-201, -202, -203, -223, -243, -301, -321, -322, -323, -341, -342, and -343 airplanes; Model A340-211, -212, -213, -311, -312, and -313 airplanes; and Model A340-541 and -642 airplanes; certificated in any category; as identified in Airbus All Operators Telex (AOT) A330-25A3272-2005, Revision 01, dated March 24, 2005; Airbus AOT A340-25A4259-2005, Revision 01; dated March 24, 2005; or Airbus AOT A340-25A5091, Revision 02, dated June 1, 2005; as applicable.

**Unsafe Condition**

(d) This AD results from a report that an emergency escape slide/slide raft (referred to hereafter as a "slide/raft") failed to deploy properly during a deployment test. We are issuing this AD to detect and correct improper routing of the electrical harnesses of certain slide/rafts, which could prevent proper deployment of the slide/raft and delay evacuation of passengers and flightcrew during an emergency.

**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.

**Inspections and Corrective Actions**

(f) Within 1,700 flight hours after the effective date of this AD: Inspect certain crew/passenger doors as required by paragraph (f)(1) or (f)(2), as applicable, of this AD to determine if slide/rafts having certain part numbers (P/N) are installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the presence of the

subject slide/rafts can be conclusively determined from that review.

(1) For Model A330-201, -202, -203, -223, -243, -301, -321, -322, -323, -341, -342, and -343 airplanes and Model A340-211, -212, -213, -311, -312, and -313 airplanes: On both right and left hand sides, inspect to determine the P/N of the slide/rafts of crew/passenger doors 1 and 4, and, only if it is a type 1 door, crew/passenger door 3. If crew/passenger door 3 is not a type 1 door, it is not subject to any requirement of this AD.

(i) If a slide/raft does not have P/N 7A1508-( ) or 7A1509-( ), no further action is required for that slide/raft by this AD.

(ii) If a slide/raft has P/N 7A1508-( ) or 7A1509-( ), before further flight, perform a general visual inspection of the electrical harness of the slide/raft and reroute the harness, as applicable, in accordance with paragraphs 4.2 through 4.2.4 of Airbus All Operators Telex (AOT) A330-25A3272-2005, Revision 01, or Airbus AOT A340-25A4259-2005, Revision 01; both dated March 24, 2005; as applicable.

(2) For Model A340-541 and -642 airplanes: On both right and left hand sides, inspect to determine the P/N of the slide/rafts of crew/passenger doors 1 and 4.

(i) If a slide/raft does not have P/N 7A1508-( ), no further action is required for that slide/raft by this AD.

(ii) If a slide/raft has P/N 7A1508-( ), before further flight, perform a general visual inspection of the electrical harness of that slide/raft and reroute the harness, as applicable, in accordance with paragraphs 4.2 through 4.2.4 of Airbus AOT A340-25A5091, Revision 02, dated June 1, 2005.

**Note 1:** For the purposes of this AD, a general visual inspection is: "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 from within touching distance unless otherwise specified. A mirror may be necessary to ensure visual access to all surfaces in the inspection area. 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."

**Actions Accomplished According to Previous Issues of AOTs**

(g) Actions accomplished before the effective date of this AD in accordance with Airbus AOT A330-25A3272, Airbus AOT A340-25A4259 (for Model A340-200 and -300 airplanes), or Airbus AOT A340-25A5091 (for Model A340-541 and -642 airplanes); all dated March 17, 2005; or A340-25A5091-2005, Revision 01, dated March 24, 2005; as applicable; are considered acceptable for compliance with the corresponding actions specified in paragraph (f) of this AD.

**Alternative Methods of Compliance (AMOCs)**

(h)(1) The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs

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**

(i) French airworthiness directive F-2005-077, dated May 11, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on September 16, 2005.

**Ali Bahrami,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 05-19235 Filed 9-26-05; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2005-22398; Airspace Docket No. 05-ASO-7]

**RIN 2120-AA66**

**Proposed Establishment of High Altitude Area Navigation Routes (RNAV); South Central United States**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** This action proposes to establish 16 high altitude area navigation (RNAV) routes in the South Central United States to support the High Altitude Redesign (HAR) program. The FAA is proposing this action to enhance safety and to improve the efficient use of the navigable airspace.

**DATES:** Comments must be received on or before November 14, 2005.

**ADDRESSES:** Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590-0001. You must identify FAA Docket No. FAA-2005-22398 and Airspace Docket No. 05-ASO-7, at the beginning of your comments. You may also submit comments through the Internet at <http://dms.dot.gov>.

**FOR FURTHER INFORMATION CONTACT:** Paul Gallant, Airspace and Rules, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-8783.

**SUPPLEMENTARY INFORMATION:**

### Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2005-22398 and Airspace Docket No. 05-ASO-7) and be submitted in triplicate to the Docket Management System (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at <http://dms.dot.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2005-22398 and Airspace Docket No. 05-ASO-7." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

### Availability of NPRM's

An electronic copy of this document may be downloaded through the Internet at <http://dms.dot.gov>. Recently published rulemaking documents can also be accessed through the FAA's Web page at <http://www.faa.gov>, or the **Federal Register's** web page at <http://www.gpoaccess.gov/fr/index.html>.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket

may also be examined during normal business hours at the office of the Regional Air Traffic Division, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

### Background

As part of the on-going National Airspace Redesign, the FAA implemented the HAR program. The HAR program's focus is to develop and implement fundamental improvements in navigation structure and operating methods to allow more flexible and efficient high altitude en route operations. In support of this program, the FAA is establishing new RNAV routes for use by suitably equipped aircraft. These new routes would allow users greater flexibility in route selection. In addition, users should achieve economic benefits derived from less restrictive routing options than are currently available in the jet route structure.

These high altitude RNAV routes will be identified by the letter prefix "Q," followed by a number consisting of from one to three digits.

### Related Rulemaking

On April 8, 2003, the FAA published the Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes, and Reporting Points rule in the **Federal Register** (68 FR 16943). The purpose of the rule was to facilitate the establishment of RNAV routes in the National Airspace System (NAS) for use by aircraft with advanced navigation system capabilities. This rule adopted certain amendments proposed in Notice No. 02-20, Area Navigation and Miscellaneous Amendments. The rule revised and adopted several definitions in FAA regulations, including Air Traffic Service Routes, to be in concert with ICAO definitions; and reorganized the structure of FAA regulations concerning the designation of Class A, B, C, D, and E airspace areas, airways, routes, and reporting points.

### The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to establish 16 RNAV routes in the South Central United

States within the airspace assigned to the Memphis Air Route Traffic Control Center (ARTCC). These routes are proposed as part of the HAR program to enhance safety, and to facilitate the more flexible and efficient use of the navigable airspace for en route instrument flight rules (IFR) operations within the Memphis ARTCC's area of responsibility.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this proposed regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

### PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005 and effective September 15, 2005, is amended as follows:

*Paragraph 2006—Area Navigation Routes.*

\* \* \* \* \*

### Q-19 PLESS to BNA [New]

PLESS ..... Fix ..... (Lat. 37°48'35" N., long. 88°57'48" W.)

|                                  |               |                                         |
|----------------------------------|---------------|-----------------------------------------|
| BNA .....                        | VORTAC .....  | (Lat. 36°08'13" N., long. 86°41'05" W.) |
| * .....                          | * .....       | * .....                                 |
| <b>Q-21 JONEZ to RZC [New]</b>   |               |                                         |
| JONEZ .....                      | Fix .....     | (Lat. 34°30'57" N., long. 95°27'34" W.) |
| RZC .....                        | VORTAC .....  | (Lat. 36°14'47" N., long. 94°07'17" W.) |
| * .....                          | * .....       | * .....                                 |
| <b>Q-23 FSM to RZC [New]</b>     |               |                                         |
| FSM .....                        | VORTAC .....  | (Lat. 35°23'18" N., long. 94°16'18" W.) |
| RZC .....                        | VORTAC .....  | (Lat. 36°14'47" N., long. 94°07'17" W.) |
| * .....                          | * .....       | * .....                                 |
| <b>Q-25 MEEOW to PXV [New]</b>   |               |                                         |
| MEEOW .....                      | Fix .....     | (Lat. 34°19'05" N., long. 93°31'25" W.) |
| ARG .....                        | VORTAC .....  | (Lat. 36°06'36" N., long. 90°57'13" W.) |
| WLSUN .....                      | WP .....      | (Lat. 37°35'00" N., long. 88°08'00" W.) |
| PXV .....                        | VORTAC .....  | (Lat. 37°55'42" N., long. 87°45'45" W.) |
| <b>Q-26 ARG to ABROC [New]</b>   |               |                                         |
| ARG .....                        | VORTAC .....  | (Lat. 36°06'36" N., long. 90°57'13" W.) |
| ABROC .....                      | Fix .....     | (Lat. 34°37'05" N., long. 87°26'07" W.) |
| <b>Q-27 FSM to ZALDA [New]</b>   |               |                                         |
| FSM .....                        | VORTAC .....  | (Lat. 35°23'18" N., long. 94°16'18" W.) |
| ZALDA .....                      | WP .....      | (Lat. 36°04'55" N., long. 93°37'37" W.) |
| <b>Q-28 GRAZN to PXV [New]</b>   |               |                                         |
| GRAZN .....                      | WP .....      | (Lat. 34°15'00" N., long. 94°21'29" W.) |
| PYRMD .....                      | WP .....      | (Lat. 34°34'00" N., long. 93°44'00" W.) |
| HAKAT .....                      | WP .....      | (Lat. 36°17'00" N., long. 91°04'00" W.) |
| ESTEE .....                      | WP .....      | (Lat. 37°41'00" N., long. 88°17'00" W.) |
| PXV .....                        | VORTAC .....  | (Lat. 37°55'42" N., long. 87°45'45" W.) |
| <b>Q-29 HARES to PXV [New]</b>   |               |                                         |
| HARES .....                      | WP .....      | (Lat. 33°00'00" N., long. 91°44'00" W.) |
| MEM .....                        | VORTAC .....  | (Lat. 35°00'54" N., long. 89°59'00" W.) |
| SIDAE .....                      | WP .....      | (Lat. 37°20'00" N., long. 87°50'00" W.) |
| PXV .....                        | VORTAC .....  | (Lat. 37°55'42" N., long. 87°45'45" W.) |
| <b>Q-30 SQS to VUZ [New]</b>     |               |                                         |
| SQS .....                        | VORTAC .....  | (Lat. 33°27'50" N., long. 90°16'38" W.) |
| VUZ .....                        | VORTAC .....  | (Lat. 33°40'13" N., long. 86°53'59" W.) |
| <b>Q-31 DHART to PXV [New]</b>   |               |                                         |
| DHART .....                      | Fix .....     | (Lat. 33°23'52" N., long. 92°25'10" W.) |
| TOROS .....                      | WP .....      | (Lat. 33°40'00" N., long. 92°10'00" W.) |
| UJM .....                        | VOR/DME ..... | (Lat. 34°34'30" N., long. 90°40'28" W.) |
| TIIDE .....                      | WP .....      | (Lat. 37°28'00" N., long. 87°59'00" W.) |
| PXV .....                        | VORTAC .....  | (Lat. 37°55'42" N., long. 87°45'45" W.) |
| <b>Q-32 ELD to SWAPP [New]</b>   |               |                                         |
| ELD .....                        | VORTAC .....  | (Lat. 33°15'22" N., long. 92°44'38" W.) |
| GAGLE .....                      | WP .....      | (Lat. 34°08'00" N., long. 90°17'00" W.) |
| CRAMM .....                      | Fix .....     | (Lat. 34°38'11" N., long. 88°53'55" W.) |
| BNA .....                        | VORTAC .....  | (Lat. 36°08'13" N., long. 86°41'05" W.) |
| SWAPP .....                      | Fix .....     | (Lat. 36°36'50" N., long. 85°10'56" W.) |
| <b>Q-33 PROWL to DHART [New]</b> |               |                                         |
| PROWL .....                      | WP .....      | (Lat. 37°02'00" N., long. 91°15'00" W.) |
| LIT .....                        | VORTAC .....  | (Lat. 34°40'40" N., long. 92°10'50" W.) |
| DHART .....                      | Fix .....     | (Lat. 33°23'52" N., long. 92°25'10" W.) |
| <b>Q-34 TXK to SWAPP [New]</b>   |               |                                         |
| TXK .....                        | VORTAC .....  | (Lat. 33°30'50" N., long. 94°04'24" W.) |
| MATIE .....                      | Fix .....     | (Lat. 34°05'42" N., long. 92°33'02" W.) |
| MEM .....                        | VORTAC .....  | (Lat. 35°00'54" N., long. 89°59'00" W.) |
| SWAPP .....                      | Fix .....     | (Lat. 36°36'50" N., long. 85°10'56" W.) |
| <b>Q-36 RZC to SWAPP [New]</b>   |               |                                         |
| RZC .....                        | VORTAC .....  | (Lat. 36°14'47" N., long. 94°07'17" W.) |
| TWITS .....                      | WP .....      | (Lat. 36°08'32" N., long. 90°54'48" W.) |
| DEPEC .....                      | WP .....      | (Lat. 36°06'00" N., long. 87°31'00" W.) |
| BNA .....                        | VORTAC .....  | (Lat. 36°08'13" N., long. 86°41'05" W.) |
| SWAPP .....                      | Fix .....     | (Lat. 36°36'50" N., long. 85°10'56" W.) |
| <b>Q-38 ROKIT to BESOM [New]</b> |               |                                         |
| ROKIT .....                      | Fix .....     | (Lat. 30°29'50" N., long. 94°30'50" W.) |
| INCIN .....                      | WP .....      | (Lat. 31°21'09" N., long. 92°45'18" W.) |
| LAREY .....                      | WP .....      | (Lat. 32°00'12" N., long. 91°22'22" W.) |
| BESOM .....                      | Fix .....     | (Lat. 33°35'11" N., long. 87°39'23" W.) |
| <b>Q-40 AEX to MISLE [New]</b>   |               |                                         |
| AEX .....                        | VORTAC .....  | (Lat. 31°15'24" N., long. 92°30'04" W.) |
| DOOMS .....                      | WP .....      | (Lat. 31°53'08" N., long. 91°09'56" W.) |
| SALVA .....                      | WP .....      | (Lat. 32°38'00" N., long. 89°21'56" W.) |
| MISLE .....                      | WP .....      | (Lat. 33°24'00" N., long. 87°38'00" W.) |

\* \* \* \* \*

Issued in Washington, DC, on September 19, 2005.

**Edith V. Parish,**

*Acting Manager, Airspace and Rules.*

[FR Doc. 05-19205 Filed 9-26-05; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 20, 510, 514, and 516

[Docket No. 2005N-0329]

**RIN 0910-AF60**

#### Designation of New Animal Drugs for Minor Uses or Minor Species

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) amended the Federal Food, Drug, and Cosmetic Act (the act) to establish new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. At this time, FDA is issuing proposed regulations to implement the act. These regulations propose procedures for designating a new animal drug as a minor use or minor species drug. Such designation establishes eligibility for the incentives provided by the MUMS act.

**DATES:** Submit written or electronic comments on this document by December 12, 2005. Submit comments on the information collection provisions by October 27, 2005.

**ADDRESSES:** You may submit comments, identified by Docket No. 2005N-0329 and/or RIN number 0910-AF60, by any of the following methods:

#### *Electronic Submissions*

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.

#### *Written Submissions*

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure timely processing of electronic comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal and agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

**Instructions:** All submissions received must include the agency name and docket number or regulatory information number for this rulemaking. All comments received may be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Andrew Beaulieu, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: [Andrew.Beaulieu@fda.gov](mailto:Andrew.Beaulieu@fda.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In enacting the MUMS act (Public Law 108-282), Congress sought to encourage the development of animal drugs that are currently unavailable to minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) in the United States or to major species afflicted with uncommon diseases or conditions (minor uses). Congress recognized that the markets for drugs intended to treat these species, diseases, or conditions are so small that there are often insufficient economic incentives to motivate sponsors to develop data to support approvals. Further, Congress recognized that some minor species populations are too small or their management systems too

diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness of these animal drugs. As a result of these limitations, sponsors have generally not been willing or able to collect data to support legal marketing of drugs for these species, diseases, or conditions. Consequently, Congress enacted the MUMS act, which amended the Federal Food, Drug, and Cosmetic Act (the act) to provide incentives to develop new animal drugs for minor species and minor uses, while still ensuring appropriate safeguards for animal and human health.

At this time, FDA is issuing proposed regulations to implement section 573 of the act (21 U.S.C. 360ccc-2). These regulations propose procedures for designating a new animal drug as a minor use or minor species drug. Such designation provides eligibility for certain incentives established by the MUMS act, including exclusive marketing rights associated with the conditional approval or approval of designated new animal drugs and for grants to support designated new animal drug development. In accordance with section 573 of the act, these proposed regulations provide for designation of a new animal drug to be granted only when the drug is intended for a minor use or use in a minor species and only when the same new animal drug, in the same dosage form, for the same intended use is not already approved under section 512 of the act (21 U.S.C. 360b), conditionally approved under section 571 of the act (21 U.S.C. 360ccc), or designated under section 573 of the act at the time that a sponsor requests designation.

The incentives in the MUMS act and these proposed regulations are modeled on those provided by the human orphan drug program. These incentives include the following: (1) Eligibility for grants and contracts to defray the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in the development of designated new animal drugs and (2) a 7-year period of exclusive marketing rights to enable sponsors to recover costs of drug development without competition. Marketing exclusivity for nondesignated drugs is limited to 3 or 5 years of protection from generic copying (section 512(c)(2)(F) of the act). The exclusive marketing rights for designated drugs provide protection from generic copying and from approval of another pioneer application for the same drug, in the same dosage form, for the same intended use.

Other major incentives of the MUMS act include the following: (1) Conditional approval, which is