

applicant may not amend or supplement an [ANDA] to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary" (MMA, Title XI, section 1101(a)(1)(B)). In part, the draft guidance clarifies the definition of "listed drug" in the context of ANDAs as directed by the MMA. Portions of the guidance addressing "listed drug" are expected to be of use to sponsors who are contemplating submitting an amendment or supplement to an existing ANDA rather than submitting a new application. The draft guidance should aid these sponsors in determining when to reference a different listed drug and, thus, when to submit a new application rather than an amendment or supplement. A situation that is not considered in this guidance is that where a pending ANDA was submitted referencing a petition approved under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(2)(C)), and another application is approved for the product described in the petition before the pending ANDA is approved. FDA has not completed its analysis of this situation, and therefore the draft guidance does not cover it.

In addition to the definition of "listed drug," the draft guidance clarifies certain other significant changes made by the MMA to provisions of the act that were originally added by the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (Hatch-Waxman). These include changes made by the MMA with respect to the availability and termination of 30-month stays of approval on ANDAs and 505(b)(2) applications under section 505(j)(5)(B)(iii) and 505(c)(3)(C) of the act, respectively, and to requirements for notice of patent certifications described by section 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the act (paragraph IV certifications). The draft guidance also clarifies the applicability of certain changes made by the MMA regarding the period described by section 505(j)(5)(B)(iv) of the act during which ANDAs with paragraph IV certifications that were not the first to be submitted cannot be approved (180-day exclusivity). Finally, this guidance explains the effective dates that apply to the MMA's amendments. FDA is aware that these changes are complex and include significant departures from previous law. The agency therefore wishes to provide guidance to industry to clarify these amendments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the agency's current thinking on the definition of "listed drug" for amendments and supplements to ANDAs, and on 30-month stays and certain other matters related to the approval of ANDAs and 505(b)(2) applications. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: October 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[USCG-2004-16860]

Gulf Landing, LLC Deepwater Port License Application

AGENCY: Coast Guard, DHS, and Maritime Administration, DOT.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The U.S. Coast Guard (USCG) and the U.S. Maritime Administration (MARAD) will hold a public hearing to receive information relevant to the issuance or denial of the requisite federal license for the proposed Gulf

Landing, LLC (Gulf Landing) Deepwater Port project. The proposed Gulf Landing Deepwater Port would be located in West Cameron Lease Block Number 213, approximately 38 miles south of Cameron, Louisiana. We encourage interested individuals and organizations to attend the public hearing and submit comments. We also seek comments from anyone unable to attend the public hearing. In conjunction with the public hearing, the USCG and MARAD will also hold an informational open house regarding the proposed Gulf Landing Deepwater Port project.

DATES: The public hearing will be held on Thursday, November 18, 2004, from 5 to 7 p.m., in New Orleans, Louisiana. The informational open house will be held on Thursday, November 18, 2004, from 3 to 4:30 p.m., at the same location in New Orleans, Louisiana. The public hearing will continue beyond 7 p.m. if necessary to ensure all individuals present at that time who wish to comment have an opportunity to do so.

Comments intended for inclusion in the public docket [USCG-2004-16860] must reach the Docket Management Facility on or before January 3, 2005.

ADDRESSES: The public hearing and informational open house will be held at the following location: Hyatt Regency New Orleans Hotel, Poydras at Loyola Avenue, New Orleans, Louisiana 70113, telephone 504-561-1234.

You may submit comments identified by Coast Guard docket number USCG-2004-16860 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

- (1) *Web Site:* <http://dms.dot.gov>.
- (2) *Mail:* Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590-0001.
- (3) *Fax:* 202-493-2251.
- (4) *Delivery:* Room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(5) Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: For further information concerning this notice, the Gulf Landing Deepwater Port license application, or the public hearing or informational open house, contact LCDR Derek Dostie, U.S. Coast Guard at (202) 267-0662 or ddostie@comdt.uscg.mil. If you have questions on viewing or submitting material to the docket, call Andrea M.

Jenkins, Program Manager, Docket Operations, telephone 202-366-0271.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

Whether or not you attend the public hearing or informational open house, we encourage you to submit written comments and related materials. All comments received will be posted, without change, to <http://dms.dot.gov> and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's "Privacy Act" paragraph below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number [USCG-2004-16860], indicate your specific concern, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period.

Viewing comments and documents: To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://dms.dot.gov> at any time and conduct a simple search using the docket number USCG-2004-16860. You may also visit the Docket Management Facility in room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit <http://dms.dot.gov>.

Public Hearing/Informational Open House

The Coast Guard and the Maritime Administration will hold a public hearing on Thursday, November 18, 2004 from 5 to 7 p.m., at the Hyatt Regency New Orleans Hotel, Poydras at Loyola Avenue, New Orleans, Louisiana 70113, telephone 504-561-1234. The informational open house will be held on Thursday, November 18, 2004 from 3 p.m. to 4:30 p.m., at the same location in New Orleans, Louisiana. We invite the public and representatives of interested agencies to attend and provide comments on the proposed license application. If you plan to attend the public hearing or informational open house and need special assistance, such as sign language interpretation or other reasonable accommodations, contact the U.S. Coast Guard as indicated in **FOR FURTHER INFORMATION CONTACT**. We ask that you make such requests at least three (3) business days before the scheduled meeting. Include a contact person's name and telephone number, your specific need, and (for persons with hearing impairments) a TDD number.

Proposed Deepwater Port Background Information

The application plan calls for construction of a deepwater port and associated anchorages in an area situated in the Gulf of Mexico, approximately 38 miles south of Cameron, Louisiana in West Cameron Lease Block Number 213, in water depth of approximately 55 feet, and adjacent to an existing shipping fairway servicing the Calcasieu River and area ports.

Gulf Landing's terminal would be capable of storing up to 200,000 cubic meters of LNG. On average, Gulf Landing expects the terminal would vaporize and deliver 1 billion cubic feet per day (Bcfd) of natural gas to the pipelines; with a peak daily send-out rate of 1.2 Bcfd. Gulf Landing proposes to construct, own, and operate up to 5 offshore pipelines, ranging from 16 to 36 inches in diameter that would traverse a combined 65.7 nautical miles. The pipelines would interconnect with existing natural gas pipelines located in the Gulf of Mexico. Gas would then be delivered to the onshore national pipeline grid for delivery to any consumption market east of the Rocky Mountains.

The project would consist of two concrete gravity base structures (GBSs) housing the LNG containment facilities, along with topside unloading and vaporization equipment, living quarters, and a ship berthing system.

The terminal would be able to receive LNG carriers with cargo capacities between 125,000 and 200,000 cubic meters and unload up to 135 LNG carriers per year. All marine systems, communication, navigation aids and equipment necessary to conduct safe LNG carrier operations and receiving of cargo during specified atmospheric and sea states would be provided at the port.

The regasification process would consist of lifting the LNG from storage tanks, pumping the cold liquid to pipeline pressure, subsequent vaporization of the LNG across heat exchanging equipment, and send-out through custody transfer metering to the gas pipeline network. No gas conditioning is required for the terminal since the incoming LNG would be pipeline quality.

License Application Background Information

The Gulf Landing Deepwater Port license application was submitted to the Secretary of Transportation on November 3, 2003. The license application calls for construction of the Gulf Landing Deepwater Port to be located in West Cameron Lease Block Number 213 approximately 38 miles south of Cameron, Louisiana. Additional information concerning the contents of the application can be found online at <http://dms.dot.gov> under docket number USCG-2004-16860, or in the notice of application published in the **Federal Register** at 69 FR 14 (Jan. 22, 2004), pages 3165-3167. This public hearing is being held pursuant to 33 U.S.C. 1504(g) to receive information relevant to the issuance or denial of the requisite federal license for the proposed Gulf Landing, LLC Deepwater Port project.

Procedural

The public meeting will be structured to provide interested members of the public with an opportunity to present comments regarding the license application. Speakers at the public meeting will be recognized in the following order: elected officials, public agencies, individuals or groups in the sign-up order, and anyone else who wishes to speak. Speakers may be asked to limit their oral comments to five (5) minutes in order to afford everyone an opportunity to speak. Any person who wishes may appear and speak or present evidence at this public hearing. Persons planning to speak at the hearing should contact the U.S. Coast Guard as indicated in **FOR FURTHER INFORMATION CONTACT**, any time prior to the hearing. Written statements and exhibits may be submitted in place of or in addition to

oral statements and will be made a part of the hearing record. Written statements and exhibits may be delivered before or during the hearing, or they may be submitted for up to 45 days following the date of the hearing to the Docket Management Facility listed under **ADDRESSES**.

Dated: October 29, 2004.

Joseph J. Angelo,

Director of Standards, Marine Safety, Security, and Environmental Protection, U.S. Coast Guard.

Richard Lolich,

Acting Director, Office of Ports and Domestic Shipping, U.S. Maritime Administration.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Draft Revised Recovery Plan for the Laysan Duck (*Anas laysanensis*)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability for review and comment.

SUMMARY: The U.S. Fish and Wildlife Service (we) announces the availability of the Draft Revised Recovery Plan for the Laysan Duck (*Anas laysanensis*) for public review and comment.

DATES: Comments on the draft revised recovery plan must be received on or before January 3, 2005.

ADDRESSES: Copies of the draft revised recovery plan are available for inspection, by appointment, during normal business hours at the following location: U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3-122, Honolulu, Hawaii 96850 (telephone: (808) 792-9400). Requests for copies of the draft revised recovery plan and written comments and materials regarding this plan should be addressed to the Field Supervisor, Ecological Services, at the above Honolulu address. An electronic copy of the draft revised recovery plan is also available at <http://endangered.fws.gov/recovery/index.html#plans>.

FOR FURTHER INFORMATION CONTACT: Holly Freifeld, Fish and Wildlife Biologist, at the above Honolulu address.

SUPPLEMENTARY INFORMATION:

Background

Recovery of endangered or threatened animals and plants is a primary goal of the Endangered Species Act (Act) (16 U.S.C. 1531 *et seq.*) and our endangered species program. Recovery means improvement of the status of listed species to the point at which listing is no longer required under the criteria set out in section 4(a)(1) of the Act. Recovery plans describe actions considered necessary for the conservation of the species, establish criteria for downlisting or delisting listed species, and estimate time and cost for implementing the measures needed for recovery.

The Act requires the development of recovery plans for endangered or threatened species unless such a plan would not promote the conservation of the species. Section 4(f) of the Act requires that public notice, and an opportunity for public review and comment, be provided during recovery plan development. We will consider all information presented during the public comment period on each new or revised recovery plan. Substantive technical comments may result in changes to a recovery plan. Substantive comments regarding recovery plan implementation may not necessarily result in changes to the recovery plans, but will be forwarded to appropriate Federal agency or other entities so that they can take these comments into account during the course of implementing recovery actions. Individual responses to comments will not be provided.

The Laysan duck is federally listed as endangered and is also listed as endangered by the State of Hawaii. This species currently is found only on the small island of Laysan in the Northwestern Hawaiian Islands, but it was also known historically from the island of Lisianski, and bones or fossils have been found in the Main Hawaiian Islands on Hawaii, Maui, Molokai, Oahu, and Kauai, indicating it previously had a much wider distribution. The Main Hawaiian Island populations of this species likely were extirpated by nonnative mammalian predators around the time of human settlement. The Laysan duck's current population is estimated to be 459 birds, but its numbers on Laysan have fluctuated from 7 to 688 adult birds during the past century. This species uses all available habitats on Laysan, including coastal areas, a hypersaline lagoon, mudflats, and densely vegetated upland areas. It eats a variety of arthropods, sometimes seeds, leaves, and algae, and at certain seasons

consumes large quantities of aquatic midge larvae. The primary threats to this species are its small population size and restricted range, stochastic fluctuations in food availability that cause its numbers to vary, potential inbreeding depression and disease susceptibility, and storms that could cause direct mortality and destroy the duck's habitat on the single low-lying island to which it is currently restricted.

The recovery goals are to conserve and recover the Laysan duck to the point where it can be downlisted (reclassified from endangered to threatened status) and eventually to delist the species (remove it from the List of Endangered and Threatened Wildlife and Plants). The objectives by which these goals will be met are to protect the existing population on Laysan and reestablish additional viable populations of the duck in areas that are managed to be free of predators. To accomplish these objectives, this recovery plan outlines high priority tasks that fall generally into four categories. First, the duck population on Laysan must be monitored and its habitat restored and protected. Second, wild juvenile ducks must be translocated to appropriate predator-free Northwestern Hawaiian Islands and eventually to sites in the Main Hawaiian Islands where predators are effectively controlled. Translocated populations must be closely monitored and managed to enhance population growth. Third, a captive propagation program must be initiated, with the aim of producing Laysan ducks for release primarily at predator-controlled Main Hawaiian Island sites. Fourth, further research must be undertaken on the life history, demography, disease susceptibility, and genetics of the Laysan duck to refine the recovery criteria and management techniques for this species.

Public Comments Solicited

We solicit written comments on the draft revised recovery plan described. All comments received by the date specified above will be considered prior to approval of this plan.

Authority: The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: August 12, 2004.

David J. Wesley,

Acting Regional Director, Region 1, U.S. Fish and Wildlife Service.

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