

in labeling. Accordingly, such studies may be submitted as abbreviated reports or synopses, and this guidance is intended to facilitate their submission. This guidance is intended to provide guidance on the types of studies that may be submitted in abbreviated reports or synopses. The guidance also provides recommendations on the formats that should be used.

In the **Federal Register** of September 21, 1998 (63 FR 50241), FDA announced that it was submitting to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA) the collection of information entitled "Application for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910-0001)." In that notice, FDA stated that the draft guidance entitled "Submission of Abbreviated Reports and Synopses in Support of Marketing Applications" (a notice announcing the availability of the draft guidance was published in the same issue of the **Federal Register**) would reduce the industry burden for submitting marketing applications under § 314.56 (21 CFR 314.50). FDA estimated that this reduction in burden would be approximately 300 hours, and reduced the industry burden estimate for § 314.50 accordingly. The **Federal Register** notice also requested comments on the burden estimates for part 314 (21 CFR part 314). OMB received no comments on the notice and approved the information collection for part 314 until November 30, 2001. In addition, none of the comments received in response to the notice announcing the availability of the draft guidance pertained to information collection issues under the PRA.

This guidance represents the agency's current thinking on submission of full study reports, abbreviated reports, and synopses of information related to effectiveness for new drugs and biological products. 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, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 19, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Program Support Center; Agency Information Collection Activities: Proposed Collections; Comment Request

The Department of Health and Human Services, Program Support Center (PSC), will periodically publish summaries of proposed information collection projects and solicit public comments in compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995. To request more information on the project or to obtain a copy of the information collection plans and instruments, call the PSC Reports Clearance Officer on (301) 443-2045.

*Comments are invited on:* (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

1. HHS Payment Management System Forms (PSC-270, formerly PMS-270) and (PSC-272, formerly PMS-272)—0937-0200—Extension

The PSC-270 (formerly PMS-270), Request for Advance or Reimbursement is used to make advances or reimbursement payments to grantees. It serves in place of the SF-270. Respondents: State and local governments; profit and nonprofit businesses and organizations receiving grants for HHS; Total Number of Respondents: 10; Frequency of Response: monthly; Average Burden per Response: 15 minutes; Estimated Annual Burden: 30 hours.

The PSC-272 (formerly PMS-272), Federal Cash Transactions Report, is used to monitor Federal cash advances to grantees and obtain Federal cash disbursement data. It serves in place of the SF-272. Respondents: State and local governments, profit and nonprofit businesses and institutions receiving

grants from HHS; Total Number of Respondents: 16,800; Frequency of Response: quarterly; Average Burden per Response: 4 hours; Estimated Annual Burden: 268,800 hours.

Total Burden: 268,830 hours.

Send comments to Norman E. Prince, Jr., Acting PSC Reports Clearance Officer, Room 17A08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 3, 1999.

**Lynnda M. Regan,**

*Director, Program Support Center.*

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Notice to Reopen the Public Comment Period for the Draft Recovery Plan for the Giant Garter Snake (*Thamnophis gigas*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of reopening of public comment period.

**SUMMARY:** The U.S. Fish and Wildlife Service gives notice that the comment period announced in the July 2, 1999 (64 FR 36033), notice of availability of the Draft Recovery Plan for the Giant Garter Snake (*Thamnophis gigas*) will be reopened for an additional 30 days. Substantial public interest in the draft plan led the Service to distribute additional copies and to provide additional opportunities for the public to comment on the plan. This draft recovery plan contains recovery criteria and actions for threatened giant garter snake. Additional species of concern that will benefit from recovery actions taken for the giant garter snake are also discussed in the draft plan. The Service reopens the comment period and solicits review and comment from the public on this draft plan.

**DATE:** Comments on the draft recovery plan received by October 13, 1999 will be considered by the Service.

**ADDRESSES:** Copies of the draft recovery plan are available for inspection, by appointment, during normal business hours at the following location: U.S. Fish and Wildlife Service, Sacramento Fish and Wildlife Office, 2800 Cottage Way, W-2605, Sacramento, California (telephone (916) 414-6600); and U.S. Fish and Wildlife Service, Regional Office, Ecological Services, 911 NE. 11th Avenue, Eastside Federal Complex,

Portland, Oregon 97232-4181 (telephone (503) 231-2071). Requests for copies of the draft recovery plan and written comments and materials regarding this plan should be addressed to Wayne S. White, Field Supervisor, Ecological Services, at the above Sacramento address.

**FOR FURTHER INFORMATION CONTACT:** Diane Elam, Fish and Wildlife Biologist, at the above Sacramento address.

**SUPPLEMENTARY INFORMATION:**

**Background**

Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the Service's endangered species program. To help guide recovery efforts, the Service is working to prepare recovery plans for most of the listed species native to the United States. 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 recovery measures needed. The Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) (Act), requires the development of recovery plans for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act as amended in 1988 requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during the public comment period prior to approval of each new or revised recovery plan. Substantive technical comments will result in changes to the plan. Substantive comments regarding recovery plan implementation may not necessarily result in changes to the recovery plan, but will be forwarded to appropriate Federal or other entities so that they can take these comments into account during the course of implementing recovery actions. Individualized responses to comments will not be provided.

The giant garter snake is an endemic species of wetlands in the Central Valley of California. Historically, giant garter snakes were found in the Sacramento and San Joaquin Valleys from the vicinity of Butte County southward to Buena Vista Lake, near Bakersfield in Kern County. Today, populations of the giant garter snake are found in the Sacramento Valley and isolated portions of the San Joaquin Valley. They historically inhabited

natural wetlands and now occupy a variety of agricultural, managed, and natural wetlands including their waterways and adjacent uplands. This species is threatened by historic wetland habitat loss and resulting habitat fragmentation, and by continuing urban expansion. The objective of this draft recovery plan is to delist the giant garter snake through implementation of a variety of recovery measures including (1) habitat protection; (2) public participation, outreach and education; (3) habitat management and restoration; (4) surveying and monitoring; and (5) research.

**Public Comments Solicited**

The Service solicits written comments on the draft 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: September 3, 1999.

**Elizabeth H. Stevens,**

*Acting Manager, California/Nevada Operations Office, Sacramento, California.*  
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**DEPARTMENT OF THE INTERIOR**

**Bureau of Land Management**

**[UT080-09-1310-00]**

**Intent To Prepare an Environmental Assessment for Amending the Book Cliffs Resource Management Plan, Utah**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Intent to prepare an environmental assessment for amending the Book Cliffs Resource Management Plan (RMP) by changing oil and gas leasing categories on crucial mule deer winter range.

**SUMMARY:** Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Utah Bureau of Land Management, Vernal Field Office will be writing an Environmental Assessment (EA) on a proposed amendment to the Book Cliffs RMP that covers portions of Uintah County, Utah. The amendment would change the oil and gas leasing category on 162,500 acres of crucial mule deer winter range from Category 1 (Standard Stipulations) to Category 2 (Special stipulations) for protection of mule deer. Protective measures would include seasonal restrictions,

rehabilitation requirements, siting of oil and gas wells, clustering of wells to reduce habitat disturbance and fragmentation, and other mitigative measures.

Alternatives identified at this time include the proposed action and the no action alternatives. Issues to be analyzed include impacts on wildlife, minerals, cultural resources and special status plants and animals. Potential impacts on Northern Ute tribal interests also will be considered.

**DATES:** Public scoping comments relating to issues and potential additional alternatives will be accepted for 30 days following the publication date of this notice. Comments must be submitted on or before October 13, 1999.

**ADDRESSES:** Scoping comments should be sent to Field Office Manager, Bureau of Land Management, Vernal Field Office, 170 South 500 East, Vernal, Utah 84078, ATTN: Book Cliffs RMP Amendment for Oil and Gas Leasing Categories on Crucial Deer Winter Range.

Comments, including names and street addresses of respondents will be available for public review at the BLM Vernal Field Office and will be subject to disclosure under the Freedom of Information Act (FOIA). They may be published as part of the Environmental Assessment and other related documents. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review and disclosure under the FOIA, you must state this prominently at the beginning of your written comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

**SUPPLEMENTARY INFORMATION:** In 1992, the Utah Division of Wildlife Resources, in consultation with BLM wildlife biologists updated big game habitat delineations in the Book Cliffs. The updated delineations were the result of new and more detailed habitat information provided by field biologists. Analysis of this new information permitted more accurate identification and expansion of the boundaries of crucial mule deer winter range. Because mule deer crucial winter range has now been identified in areas presently offered for oil and gas leasing without protective measures for mule deer, a plan amendment is being considered.