United States Department of the Interior

BUREAU OF LAND MANAGEMENT
Nevada State Office
1340 Financial Boulevard
Reno, Nevada 89502-7147
https://www.blm.gov/nevada

In Reply Refer To:
4720/4710.4(NV930)

MAR 0 6 2020

DECISION RECORD

The Bureau of Land Management (BLM) Nevada State Office (NSO) proposes to conduct a Population Growth Suppression study that would test the contraceptive effects of an oocyte growth factor (OGF) vaccine using previously-captured excess wild horses in cooperation with United States Department of Agriculture, Animal and Plant Health Inspection Services National Wildlife Research Center (NWRC). The NSO has determined that testing a one-dose formulation of OGF vaccine, with research conducted by the NWRC, would provide useful information about this potential fertility control method. If the vaccine is effective, then it could cause infertility for at least three years. A one-dose fertility control vaccine could be useful in some cases, in reducing wild horse herd growth rates in BLM-administered herd management areas (HMAs) across the west. The use of fertility controls, including sterilization, is authorized under the Wild Free-Roaming Horses and Burros Act of 1971 (Public law 92-195), as amended (WFRHBA) (16 U.S.C. 1333 section 3.b.1).

BLM has prepared a Final Environmental Assessment (EA) (DOI-BLM-NV-0000-2020-0001-EA) for a proposed study to test the effectiveness of a one-injection formulation of the OGF vaccine. The Final EA is consistent with BLM's management responsibilities under the RHBA, applicable regulations at 43 CFR § 4700, and BLM policies, and with the Carson City Consolidated Resource Management Plan (2001).

The Proposed Action (Alternative 1) would test, in a small number of captive wild horses already removed from the range as excess, the efficacy of a vaccine against two oocyte growth factors (GDF9 and BMP15), where the vaccine has been formulated to cause long-lasting contraception from a single dose. A complete description of the proposed study is in the Final EA. The test would take place at the Northern Nevada Correctional Center (NNCC). NNCC is a prison facility located in Carson City, Nevada, where BLM has an existing contract to provide wild horse training and housing services. The facility is well suited to the study design and have been used in the 2011-2013 pen trial of pelleted version of a PZP vaccine that also included wild mares and stallions in breeding groups. The horses would be chosen from those already removed from BLM HMAs after having being identified as excess animals through previous agency decisions. The study would monitor fertility of 16 captive wild mares treated with the OGF vaccine and 16

or more untreated wild mares, over three years. A smaller number of wild fertile stallions would live with the mares to allow for breeding. A previously tested version of this vaccine caused contraception for at least 2 years, but it used a weak vaccine adjuvant that required multiple doses to be effective.

Alternative 2. Under this No Action alternative, the one-dose OGF vaccine would not be tested.

DECISION

It is the NSO decision to implement the Proposed Action (Alternative 1) as described in the Final EA (DOI-BLM-NV-0000-2020-0001-EA). The effective date of this decision is 31 days from the date of the authorized officer's signature on this document (43 CFR Part 4.21).

The study is designed to test the efficacy of the one-dose OGF vaccine, over a three-year period. The one-dose formulation of ovarian growth factor vaccine which includes two antigens, BMP15 and GDF9, that have been identified as having a role in oocyte development in the ovary, along with other vaccine components to increase the vaccine's immune response. Sixteen mares would be treated with the fertility control vaccine, and 16 mares would serve as untreated "controls" for comparison. Mares would be housed in four groups of eight, with each group in a separate holding pen with one fertile stallion. The mares' response to the vaccination would be measured through pregnancy check examinations, and hormone and antibody concentrations in blood samples.

RATIONALE

In 2013 the National Academy of Science (NAS) released a report titled "Using science to improve the BLM Wild Horse and Burro Program; a Way Forward." One of the conclusions in the NAS Report was that it could be useful to have a long-lasting fertility control method available for some situations in wild horse and burro management. BLM has a long record of funding development and testing of long-lasting fertility control methods. While there are several fertility control vaccines available for BLM to use (PZP Zonastat-H, PZP-22 vaccine pellets, and GonaCon), those vaccines have limited duration of effect, especially if only one dose of the vaccine is given to the mare.

The study proposed and described in the Final EA would test a fertility control method (the one-dose OGF vaccine) that may be responsive to the search for a contraceptive vaccine with longer-lasting effects caused by only one dose of vaccine. A previous version of the OGF vaccine that would be used in this research has already been tested in domestic horses and appeared safe and effective (Final EA Appendix A). Compared to that OGF vaccine, the one-dose vaccine formulation in this study would merely use a different adjuvant and antigen packaging preparation, both of which are intended to cause a longer-lasting immune response.

Upon analyzing the impacts of the Proposed Action (Alternative 1) and the No Action alternative (Alternative 2) following issuance of the preliminary EA for public review, it has been determined that implementing the Proposed Action (Alternative 1) will not have a significant impact to the human environment and that an environmental impact statement is not required as set forth in the attached Finding of No Significant Impact.

The study is necessary to determine whether the one-dose OGF vaccine may be a reliable, long-lasting fertility control method for future BLM wild horse and burro herd management actions. Any such future management actions, however, would be subject to separate decisions by BLM and would be covered under separate NEPA compliance. Conducting nondestructive research and seeking the recommendations of qualified scientists on matters related to wild horse and burro management is consistent with the provisions of the WFRHBA and 43 CFR 46.210(e).

Not conducting the proposed study under the No Action Alternative would lead to the BLM having no additional or reliable information about the contraceptive effects of the one-dose OGF vaccine. If this proposed study does not take place, future BLM decisions about on-range application of the one-dose OGF vaccine may need to be made in the absence of information that would have come from this study. Completion of this proposed study is not a necessary pre-requisite to future on-range management actions that might propose use of this or another formulation of OGF vaccine, as those actions would be subject to site-specific analysis and NEPA requirements, including analysis of any information that might be available at that time from this study or other sources regarding the OGF vaccine.

PUBLIC INVOLVEMENT

A Preliminary EA was made available to interested individuals, agencies and groups for a 15-day public review and comment period on December 5-20, 2019. Comments were received from 44 individuals, groups, and agencies. Many of these comments contained overlapping issues/concerns which were consolidated into a smaller number of distinct topics. Appendix E of the Final EA provides a detailed summary of the comments received, and BLM's responses. The Final EA/ Oocyte Growth Factor Vaccine Study is available on the National NEPA Registrar web page at https://go.usa.gov/xpEvc or by contacting the Nevada State Office.

APPEALS

If you wish to appeal this decision, it may be appealed to the Interior Board of Land Appeals, Office of the Secretary, in accordance with 43 CFR part 4 and Form 1842-1 (enclosed). If you appeal, your appeal must also be filed with the Bureau of Land Management at the following address:

BLM Nevada State Office
Attn: OGF Vaccine Appeal
1340 Financial Boulevard
Reno, Nevada 89502

Your appeal must be filed within thirty (30) days from receipt or issuance of this decision. You have the burden of showing that the decision appealed from is in error.

If you wish to file a petition pursuant to regulation 43 CFR 4.21 (58FR 4942, January 19, 1993) for a stay (suspension) of the decision during the time that your appeal is being reviewed by the Board, the petition for stay must accompany your notice of appeal. Copies of the notice of appeal and petition for a stay must also be submitted to:

Board of Land Appeals
Dockets Attorney
801 N. Quincy street, Suite 300
Arlington, VA 22203

A copy must also be sent to the appropriate office of the Solicitor at the same time the original documents are filed with the above office.

US Department of the Interior
Office of the Regional Solicitor
Pacific Southwest Region
2800 Cottage way, Room E-1712
Sacramento, California 95825

If you request a stay, you have the burden of proof to demonstrate that a stay should be granted. A petition for a stay is required to show sufficient justification based on the following standards:

1. The relative harm to the parties if the stay is granted or denied
2. The likelihood of the appellant's success on the merits
3. The likelihood of immediate and irreparable harm if the stay is not granted
4. Whether the public interest favors granted the stay.

The Office of Hearings and Appeals regulations do not provide for electronic filing of appeals, therefore they will not be accepted

Sincerely

Jon K Raby
State Director

UNITED STATES
DEPARTMENT OF THE INTERIOR
BUREAU OF LAND MANAGEMENT
NEVADA STATE OFFICE
FINDING OF NO SIGNIFICANT IMPACT
FOR
Oocyte Growth Factor Vaccine Study

I have reviewed Final Environmental Assessment (EA) DOI-BLM-NV-0000-2020-0001-EA, dated March 6, 2020. After consideration of the environmental effects as described in the Final EA, and incorporated herein, I have determined that the proposed action with the project design specifications, including minimization or mitigation measures identified in the Final EA, will not significantly affect the quality of the human environment and that an Environmental Impact Statement (EIS) is not required to be prepared.

This finding and conclusion is based on my consideration of the Council on Environmental Quality's (CEQ) criteria for significance (40 CFR 1508.27), both with regard to the context and the intensity of impacts described in the Final EA.

Context:
The affected region is limited to Carson City County, Nevada, on the grounds of the Northern Nevada Correctional Center (NNCC). BLM contracts with NNCC to provide wild horse training, housing, and care. The Final EA has been developed with input from interested members of the public.

Intensity
Based on my review of the Final EA against CEQ's factors for intensity, there is no evidence that the impacts are significant:

1. Impacts that may be both beneficial and adverse.

The Final EA (chapter 4) considered potential beneficial and adverse effects of the proposed action (Alternative 1).

2. The degree to which the proposed action affects public health and safety.
The BLM's Comprehensive Animal Welfare Program standards for off-range corrals (Final EA, Appendix C) would be used to conduct animal handling and care, and are designed to protect human health and safety, as well as the health and safety of wild horses. During operations, the Lead Contracting Officers Representative (COR) for the BLM contract with the NNCC would be present, or would delegate supervision duties to another BLM employee. BLM will arrange for on-call veterinary oversight by a local veterinarian. Individuals handling the oocyte growth factor (OGF) vaccine will take standard precautionary steps used when handling any vaccine, to minimize the risk of needle sticks. Out of an abundance of caution, no female humans of childbearing age or younger will be involved with the handling or injection of vaccine during this study.

3. Unique characteristics of the geographic area such as proximity of historic or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

The proposed action has no potential to affect unique characteristics such as historic or cultural resources or properties of concern to Native Americans. There are no wild and scenic rivers, or ecologically critical areas present in the areas.

4. The degree to which the effects on the quality of the human environment are likely to be highly controversial.

"Controversy" in this context means scientific or technical controversy about the nature of the effects, not expressions of opposition to the proposed action(s) or preference among the alternatives. BLM has responded to all public comments in Final EA Appendix E. Some of the most commonly voiced points of opposition identified through the public comment period were concerns stating that: 1) BLM should not pursue development of this particular fertility control vaccine but should use porcine zona pellucida (PZP) vaccine in wild horse management instead; 2) testing the OGF vaccine would lead to future BLM management actions that would undermine the self-sustaining nature of managed wild horse populations on public rangelands; 3) the study would not be useful in assessing behavioral effects of OGF vaccination in the wild; 4) the proposed three-year study duration was inadequate to test long-term effects of the OGF vaccine; and 5) BLM should further analyze the expected physiological effects of the vaccine.

The first and second types of concerns reflect preferences about BLM's possible future on-range management actions, yet those are beyond the scope of this decision, and are not about a controversy as defined in this context. No on-range wild horse management is analyzed in this Final EA. On-range application of any wild horse fertility control method in the future would be subject to site-specific analysis and NEPA. The proposed study analyzed in this Final EA does not set precedent for any such future BLM decision. The third and fourth types of concerns appear to reflect the view that the study does not address all the questions that the commenters would like to have answered if they were in the position of choosing whether to use or not use the OGF vaccine as part of future on-range wild horse herd management decisions. Statements about individuals' preferred study goals and study designs are not a controversy in this context. Again, any such future on-range herd management decisions are beyond the scope of this decision, and would be subject to site-specific analysis and NEPA. Regarding the fifth type of concern, there is no scientific controversy about the nature of the anticipated physiological effects of the OGF vaccine. As analyzed in the Wild Horse and Burro section of chapter 4 in the attached Final EA, vaccination with the OGF vaccine is expected to cause disruption in oocyte and follicular development, leading to a cessation of ovulation, a potential lack of estrus cycling, and related hormonal effects consistent with a lack of cycling and estrus. The effects, whether temporary or long-lasting, are expected to be comparable to what is observable in mares' seasonal anestrous period, in that during shorter days of fall, winter and early spring, the ovaries of untreated mares are healthy, but minimally active. As noted in the Final EA, there was an initial study conducted with a different formulation of the OGF vaccine. That formulation required four doses to be effective, but the outcome was infertility, disruption of ovarian follicle development, and a cessation of estrus cycling. Those were the intended consequences, and those are also the expected consequences of the one-dose OGF vaccine formulation. The action of using the vaccine is not controversial, because there is no reason to expect general outcomes of vaccination other than either vaccine success or failure, in terms of contraceptive efficacy, in individual treated mares.

5. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.

Possible effects on the human environment are not highly uncertain and do not involve unique or unknown risks. For an action's effects to be "highly uncertain" there must be more than just "some uncertainty." Here, there are few uncertainties. As noted in response #4 above, vaccination with the OGF vaccine is expected to cause disruption in oocyte and follicular development, leading to a cessation of ovulation, a potential lack of estrus cycling, and related hormonal effects consistent with a lack of cycling and estrus. The effects are expected to be comparable to what is observable in mares' seasonal anestrous period, when the ovaries of untreated mares are healthy, but minimally active. The central uncertainty is only whether or not individual vaccine-treated mares do, or do not, become infertile as a result of vaccination. There is good reason to test the efficacy of the vaccine, but the set of possible outcomes is clearly identified.

6. The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration.
The Proposed Action only applies to the excess wild horses that have already been removed from the range and are selected for the research project. Any future proposal by BLM to use the OGF vaccine analyzed in this Final EA would be subject to separate NEPA compliance and separate decisions.

7. Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.
The Proposed Action is not related to other actions with individually insignificant but cumulatively significant impacts. The proposed study analyzed in this Final EA does not set precedent for any future BLM decision.

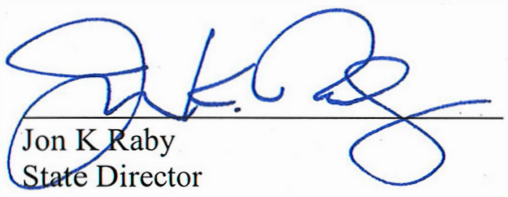
8. The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed in or eligible for listing in the National Register of Historic Places or may cause loss or destruction of significant scientific, cultural, or historic resources.
The Proposed Action has no potential to adversely affect significant scientific, cultural, or historical resources.

9. The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.
There are no known threatened or endangered species, or their habitat affected by the Proposed Action.

10. Whether the action threatens a violation of Federal, State, or Local law or requirements imposed for the protection of the environment.
The Proposed Action is in compliance with the Carson City District Resource Management Plan, which provides direction for the protection of the environment on public lands; the Federal Land Policy and Management Act (FLPMA) of 1976, which establishes the agency's multiple-use and sustained yield mandate; 43 CFR 46.210 (e), which allows for study, research, and monitoring activities; the Public Rangelands Improvement Act (43 U.S.C. 1901) (1978), which establishes a policy and commitment to manage, maintain, and improve the condition of the public rangelands so that they become as productive as feasible for all rangeland values; and the Wild Free-Roaming Horses and Burros Act of 1971 (Pub. L. 92-195) as amended, specifically, but not limited to, the following sections:

1333. Powers and duties of the Secretary.

(3) For the purpose of furthering knowledge of wild horse and burro population dynamics and their interrelationship with wildlife, forage and water resources, and assisting the Secretary in the determination as to what constitutes excess animals, the Secretary shall contract for a research study of such animals with such individuals independent of Federal and State government as may be recommended by the National Academy of Sciences for having scientific expertise and special knowledge of wild horse and burro protection, wildlife management and animal husbandry as related to rangeland management.



Jon K Raby
State Director

3/5/2020
Date