

## **APPENDIX A**

### **SUMMARY OF FERTILITY CONTROL METHODOLOGY Specific to McCullough Peaks HMA**

#### **1. PROPOSED FERTILITY CONTROL AGENT:**

At this time, all published research indicates that the Immunocontraceptive Porcine Zona Pellucida (PZP) vaccine meets BLM requirements for an ideal contraceptive agent including criteria for safety and efficacy. When injected, PZP vaccine acts as an antigen and causes the mare's immune system to produce antibodies. These antibodies then bind to eggs in the mare's ovaries and effectively block sperm binding and fertilization. The vaccine is relatively inexpensive (\$20 per dose), can be remotely administered in the field, and requires a single annual booster dose to confer infertility for one breeding season. Research has shown that contracepted mares clearly show improvements in body condition and may actually live longer. From a mare physiological standpoint, PZP contraception appears to be completely reversible, does not appear to cause out-of-season births, and has no ill effects on ovarian function if contraception is not repeated for more than 5 consecutive years on a given mare.

If mares are already pregnant, research has shown that PZP vaccine will not affect normal development of the fetus, hormone health of the mare or behavioral responses to stallions. Recent behavioral studies with the Assateague Island and Shackleford Banks wild horses have shown that contracepted and uncontracepted mares had virtually identical activity budgets, associated in a similar manner with the harem stallion and showed no increase in harem exchange behavior or change in their social status during the study. All mares affected by the proposed action would continue to be monitored for body condition and aspects of social behavior. The latter would be compared to existing baseline data and control studies.

#### **2. VACCINE QUALITY and REMOTE-DELIVERY PROTOCOL:**

All PZP vaccine used on mares within the McCullough Peaks HMA would be provided by the Science and Conservation Lab (SCC), ZooMontana and subjected to quality control testing. All documented aspects of PZP vaccine provision, mare selection, vaccine remote-delivery, dart recovery, record keeping, veterinary emergencies, and media relations would be strictly adhered to by all participants in the proposed action. These protocol shall serve as the Standard Operating Procedures (SOPs) for the proposed management action. Implementation of the SOPs would take into consideration all safety concerns, individual animal health and condition, seasonal distribution of the horses, as well as local weather and environmental considerations.

## II. PARTICIPANTS

Project Manager: Patricia L. Hatle, Wild Horse and Burro Specialist, CYFO, BLM

Horse Identification: Field-trained and experienced  
Susan Hahn, Seasonal Employee, USGS, BRD  
Ada Inbody, Seasonal Volunteer, USGS, BRD  
Phyllis Preator, Seasonal Employee, USGS, BRD

Vaccine Preparation: Robin Lyda, The Science and Conservation Center, ZooMontana, 2100 South Shiloh Road, Billings, MT 59106

Designated Vaccine Handlers Jay F. Kirkpatrick, Kim Frank and Robin Lyda, The Science and Conservation Center, ZooMontana, Billings, Mt.

Dr. John Turner  
Medical College of Toledo, Ohio

Ron Hall, NPO, BLM

Research Oversight: Linda Coates-Markle, BiFO, BLM  
Francis Singer, USGS, BRD  
Jason Ransom, USGS, BRD  
Dr. Al Kane, APHIS

Contract Veterinarian: Lyle Bischoff, DVM,  
Powell Veterinary Service  
522 S. Division, Powell, WY 82435

### 3. **PERMISSION and CRITERIA for VACCINE USE:**

The Humane Society of the United States (HSUS) has made the PZP vaccine available to the BLM under the Investigational New Animal Drug exemption (INAD #8857) filed with the federal Food and Drug Administration (FDA). As a condition of using the PZP vaccine, the HSUS expects the BLM to follow the Draft Criteria for Immunocontraceptive Use in Wild Horse Herds recommended by the Wild Horse and Burro National Advisory Board in August 1999.

### 4. **AUTHORITY for PROPOSED ACTION:**

The Wild Free-Roaming Horse and Burro Act of 1971 (Public Law 92-195) as amended, Section 3(b)(1), states that the Secretaries of the Interior and Agriculture shall “determine appropriate management levels of wild free-roaming horses and burros on areas of public lands; and determine whether appropriate management levels should be achieved by the removal or destruction of excess

animals, or other options (such as sterilization or natural controls on population levels).” The authority may also be found at Title 43 of the Code of Federal Regulations (CFR-4700, Protection, Management and Control of Wild and Free-Roaming Horses and Burros).

With implementation of the proposed action, selected wild horse mares would be contracepted under a humane approach for a one-year period in accord with 43 CFR 4700.0-6 which identifies that [...wild horses]" shall be managed as self-sustaining populations of healthy animals in balance with other uses and the productive capacity of their habitat.", and with Public Law (PL) 92-195 Sec 3 (b) (2) which identifies the need to maintain appropriate management levels of wild horses within their herd management area (HMA).

The BLM has developed a long-term research strategy for the Wild Horse and Burro Program. A final draft of the Strategic Research Plan was reviewed and supported by the National Wild Horse and Burro Advisory Board in August 2002, and the BLM Director’s Science Advisory Board in January 2003. Within this strategy, continuing research on fertility control is identified as a high priority and directions are provided in the National Wild Horse Fertility Control Field Trial Plan (FCFTP) (Singer and Coates-Markle, 2002). The implementation of additional fertility control field trials, under this research protocol, began in the summer 2002.

The proposed action would adhere to all guidance and research protocol set by the oversight documents. The intent of this research is to answer those remaining questions and concerns about fertility control using PZP that are best answered on free-ranging populations in the wild. The plan details protocols for injections, experimental design, and research methods that will be employed to evaluate effects of PZP on free-ranging animals. The research focuses on the effects of immunocontraceptive treatment on seasonality of foaling, any possible compensatory reproduction of mares post-treatment, duration of estrus cycles, population growth rates, and harem behavior. The behavior and fertility of the treated mares will be studied both during the treatment phase, and for a minimum of two years post-treatment to assure that a return to normal fertility occurs.

## **5. PROCEDURES**

**A. Vaccine preparation and shipment:** Vaccine would be prepared under the supervision of Robin Lyda, Science and Conservation Center (SCC), Billings, MT and transported to the field site in Wyoming on dry ice, under Food and Drug Administration authority (Investigational New Animal Drug exemption No.8857 (G0002 & 0003). FDA form “Notice of Drug Shipment” would be completed for each shipment of the PZP vaccine and filed in the offices of the Science and Conservation Center at ZooMontana, Billings, MT.

**B. Selection of subject animal:** Animals to be treated will be identified by BLM and USGS-BRD field personnel. Approximately 40 released mares will be treated within the herd. The number and identity of animals would be selected on the basis of age and social structure as per the Environmental Assessment (EA) Alternative 1: Proposed Action. All animals selected for treatment would be female and at least one year old.

### **C. Delivery of contraceptive vaccine:**

Target mares released back to the HMA would be treated with an immuno-contraceptive vaccine, Porcine zona pellucidae (PZP), administered by trained BLM personnel. The inoculation of mares would consist of a liquid dose of PZP vaccine and a time released portion of the drug in the form of pellets. The approach incorporates the PZP into a non-toxic, biodegradable material which can be formed into small pellets. The pellets are injected with the liquid and are designed to release PZP at several points in time much the way time-release cold pills work.

Delivery of the vaccine would be by means of jab stick syringe or dart with a 12 gauge needle or 1.5" barbless needle respectfully, 0.5 cc of the PZP vaccine would be emulsified with 0.5 cc of adjuvant (a compound that stimulates antibody production) and loaded into the delivery system. The pellets would be placed in the barrel of the syringe or dart needle and would be injected with the liquid. Upon impact the liquid in the chamber would be propelled into the muscle along with the pellets. This formulation would be delivered as an intramuscular injection by a jab stick syringe, while mares are restrained in the working chute. This delivery method has been used previously to deliver immuno-contraceptive vaccine with acceptable results. Administration of this two-year vaccine to mares in late summer (before November) would be expected to be 94% effective the first year, 82% the second year, and 68% the third year.

### **D. Monitoring:**

The intent of the monitoring would be to assess vaccine effects on mare estrus, foaling, body condition, behavior, fitness and survival. The use of the immunocontraceptive would adhere to well-developed research protocol, and is responsible to restrictions and requirements placed on continuing research efforts with the PZP vaccine as set by the Humane Society of the United States (HSUS), the Food and Drug Administration (FDA), Animal and Plant Health Inspection Service (APHIS) and the National Wild Horse and Burro Advisory Board.

The field trials will provide either three or four years of contraception to treated mares. Following three or four years of contraception, treated mares will be allowed to return to normal reproductive function. Their reproductive rates, behavior, and harem social structure will be observed for a minimum of two years post-treatment, to assure that normal fertility is resumed. The treated mares will be individually marked and/or be individually recognizable without error. The treated mares must be left on the range for the duration of the research, and are not likely to be treated again.

In May 2003, United States Geological Survey – Biological Research Division (USGS-BRD) biological technicians under the supervision of BRD research biologists began the field trial studies to assess effects on mare estrus, foaling, body condition, behavior, fitness and survival. Individual behavior, reproduction, survival, and any health abnormalities will be closely monitored in the individually recognized horses.

Mares in 7 or 8 harems were selected for intensive studies during the summer of 2003. Pretreatment data on harem dynamics, population dynamics, and behavior was collected in 2003

and will have been gathered for two consecutive years prior to contraception. Treated mares will be compared to untreated mares (controls) in the same harems. Multivariate models will include age of mare, year, weather, density-dependent relations, and compensatory responses. If possible, harems with no treated mares will also be observed.

As of August 1, 2004 USGS-BRD field technicians have identified and entered into WHIMS a total of 498 individuals as part of the field trial study. In conformance with the Fertility Control Field Trial Plan for Individual-Based Study Herds, individuals would be initially recognized from natural markings using a computerized photo ID system call WHIMS (Wild Horse Information Management System, USGS\_BRD, Ron Osborne, Final report to BLM 1999). Records and any photos will be maintained at the field office and a copy of the completed PZP treatment form will be sent to the National Program Office (NPO), Reno NV and the WH&B Research Coordinator and BRD-USGS.

A tracking system will be maintained by NPO detailing the quantity of PZP issued, the quantity used, the disposition of any unused PZP, and the number of treated mares by HMA, FO and State along with the freeze-mark applied by HMA. In the vast majority of cases, the released mares will never be gathered sooner than the mandatory three- year holding period. In those rare instances when, due to unforeseen circumstances, a treated mare(s) are removed from an HMA they will be maintain either in a BLM facility or a contracted Long Term Holding Facility until the expiration of the three- year holding period. In the event that it is necessary to remove treated mares, their removal and disposition will be coordinated through NPO. After expiration of the three-year holding period, the animal may be placed in the adoption system.