DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 04–129–1]

Draft Guideline on Target Animal Safety: Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence (VICH Topic GL41)

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: A draft guideline titled ''Target Animal Safety: Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence'' has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The draft guideline is intended to establish criteria and requirements for the conduct of studies that examine the potential for reversion to or increase in virulence of live veterinary vaccines in target animals. Because the draft guideline applies, in part, to veterinary biological products regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on its provisions so that we may include any relevant input on the draft in the Agency's comments to the VICH Steering Committee.

DATES: We will consider all comments that we receive on or before February 22, 2005.

ADDRESSES: You may submit comments by any of the following methods:

- EDOCKET: Go to *http://www.epa.gov/feddocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once you have entered EDOCKET, click on the ''View Open APHIS Dockets'' link to locate this document.
- Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. 04–129–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 04–129–1.
- E-mail: Address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 04–129–1'' on the subject line.
- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the instructions for locating this docket and submitting comments.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

Other Information: You may view APHIS documents published in the **Federal Register** and related information, including the names of groups and individuals who have commented on APHIS dockets, on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

You may request a copy of the draft guideline by writing to Dr. Donna M. Gatewood, Center for Veterinary Biologics, VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010, or by calling (515) 232–5785. The draft guideline is also available on the Internet at *http://www.aphis.usda.gov/vs/cvb/pel/notices*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Policy, Evaluation and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The VICH initiative is conducted under the auspices of the International Office of Epizootics. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise regarding veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based harmonized technical requirements for the development of veterinary drugs and biologics. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

This notice informs the public that the draft document ''Target Animal Safety: Examination of Live Veterinary Vaccine in Target Animals for Absence of Reversion to Virulence'' (VICH Topic GL41) has been made available by the VICH Steering Committee for comments by interested parties. The draft guideline is intended to provide a unified standard for regulatory bodies to facilitate the mutual acceptance of reversion to virulence data. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act, particularly with regard to reversion to virulence testing, we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft document reflects current APHIS thinking on examining veterinary vaccines in target animals for absence of reversion to virulence. In accordance with the VICH process, once a final draft of ''Target Animal Safety: Examination of Live Veterinary Vaccine in Target Animals for Absence of Reversion to Virulence'' has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, the final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee's final guidance document for use by U.S.

veterinary biologics licensees, permittees, and applicants. In addition, APHIS may also consider the use of the final guidance document as the basis for proposed additions or amendments to its regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final version of ''Target Animal Safety: Examination of Live Veterinary Vaccines in Target Animals for Absence of Reversion to Virulence'' may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft version.

Authority: 21 U.S.C. 151 *et seq.*

Done in Washington, DC, this 16th day of December 2004.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF AGRICULTURE

Forest Service

Chequamegon-Nicolet National Forest, Great Divide Ranger District; WI; Twentymile Restoration Project

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The USDA Forest Service, Chequamegon-Nicolet National Forest, Great Divide Ranger District intends to prepare an environmental impact statement (EIS) to disclose the environmental consequences of a vegetation and water resources restoration project. In the EIS the USDA Forest Service will address the potential environmental impacts associated with: restoring northern hardwood forests to an uneven-aged condition, improving the landscape pattern of northern hardwood forests, reducing the amount of aspen in cold-water stream corridors, reducing sediment and restoring riparian and stream habitat, improving upland forest type composition, balancing the age class distribution of aspen, and providing a safe, efficient, and effective transportation system; all while promoting healthy forests and providing forest commodities.

The Twentymile Project Area is approximately 32,000 acres in size and is located in Bayfield County, approximately 25 miles northeast of Hayward, Wisconsin. The approximate legal description for the area is as follows: T44N R6W Sections 1–14 and 23–25; T44N R5W Sections 5–8, 14–23, and 26–35; T43N R5W Sections 1–3, 11, and 12; and T43N R4W Sections 4–7. See the **SUPPLEMENTARY INFORMATION** section for the purpose and need for the action.

DATES: Comments concerning the scope of the analysis should be received within 30 days following publication of this notice to receive timely consideration in the preparation of the draft EIS. The draft environmental impact statement is expected May 2005 and the final environmental impact statement is expected September 2005.

ADDRESSES: Send written comments to Anne Archie, c/o Deb Sigmund, NEPA Coordinator; Great Divide Ranger District, P.O. Box 896, Hayward, WI 54843. Send electronic comments to: *comments-eastern-chequamegon-nicolet-great-divide@fs.fed.us.* See **SUPPLEMENTARY INFORMATION** section for information on how to send electronic comments.

FOR FURTHER INFORMATION CONTACT: Deb Sigmund, NEPA Coordinator, Great Divide Ranger District, Chequamegon-Nicolet National Forest, USDA Forest Service; telephone: 715–634–4821. See address above under **ADDRESSES**. Copies of documents may be requested at the same address. Another means of obtaining information is to visit the Forest Web page at *www.fs.fed.us/r9/cnnf/*—click on ''Natural Resources'', then ''Twentymile Restoration Project''.

SUPPLEMENTARY INFORMATION:

Purpose and Need for Action

The purpose of the Twentymile Restoration project is to implement land management activities that are consistent with direction in the Chequamegon-Nicolet National Forests Land and Resource Management Plan (Forest Plan, 2004) and to respond to specific needs and/or problems that were identified during opportunity area and transportation system analyses.

The purpose and need for this proposal is to: (1). Restore northern hardwood forests to an uneven-aged condition (Plan, p. 1–3). These uneven-aged forests are to be characterized by a variety of tree ages and sizes, with older age classes well represented. Achieve large diameter trees (>25″ dbh), and old growth characteristics such as tip-ups, snags, and coarse woody debris (Plan, p. 3–9). Emphasis for restoration is to provide a well-developed understory that provides feeding and nesting habitat for Neotropical birds, nutrient cycling, and tree seedling establishment (Plant FEIS, p. 3–61); (2.) Improve the landscape pattern of northern hardwood forests by maintaining or recreating large northern hardwood patch conditions and allowing early successional forest patches to succeed or treat them so as to encourage conversion to long-lived species (Plan, p. 3–8); (3.) Reduce the amount of aspen in cold-water stream corridors by not regenerating it and/or converting it to long-lived conifers or northern hardwoods (Plan p. 2–17); (4.) Reduce sediment deposition and restore riparian and stream habitat. Maintain or restore streams to provide for the transport of water and sediments within the natural ranges for the watershed, which results in stable stream channels (Plan, p. 3–60). Relocate existing roads and trails out of riparian management zones and eliminate stream crossings when practicable (Plan pp. 1–3 and 2–2); (5.) Improve upland forest type composition. Terrestrial ecosystems should be in healthy, diverse, and productive conditions and support a diversity of plant and animal communities and tree species (Plan, p. 1–3); (6.) Balance the age class distribution of aspen in the areas it is desired to promote diversity for various wildlife species. A long-term sustainable level of all age classes is needed by wildlife species for dense cover and forage (Plan, p. 2–4 and 3–11); (7.) Promote healthy forests and provide forest commodities. Maintain and enhance the growth and vigor of trees within the project area, while providing a variety of wood products and species mixes for the different market niches through commercial timber harvests (Plan, p. 1–6); (8.) Provide a safe, efficient, and effective transportation system. A desirable transportation system provide safe access and meets the needs of communities and forest users; facilitates the implementation of the Forest Plan; allows for economical and efficient management within likely budget levels; meets current and future resource management objective; and has a minimal impact on natural resources. (Plan, pp. 1–7 and 2–35–38; Twentymile Roads Analysis, p. 4).

Proposed Action

The following actions have been identified to address the above needs. (1) To address the need for restoration of northern hardwood forest, approximately, 7,897 acres of predominantly even-aged northern hardwood stands would be selectively harvested. Approximately 20 acres of these northern hardwood stands would also be under planted to white pine. Within approximately 576 acres of these stands, some of the trees marked for