ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 00–116–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238.
Please state that your comment refers to Docket No. 00–116–1.

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.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

You may request a copy of the draft guideline ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports'' by writing to or calling the person listed under **FOR FURTHER INFORMATION CONTACT**.

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

SUPPLEMENTARY INFORMATION: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the International Office of Epizootics (OIE, the Office International des Epizooties) 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 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 biological products. 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.

The draft document that is the subject of this notice, ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports'' (VICH Topic GL24), has been made available by the VICH Steering Committee for comments by interested parties. The draft guideline, which defines pharmacovigilance of veterinary medicinal products as the detection and investigation of the effects of veterinary medicinal products, mainly aimed at safety and efficacy in animals and safety in people exposed to these products, deals with the spontaneous reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to adverse event reports—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 the generation and submission of adverse event reports concerning veterinary biological products. (The draft guideline refers to such products as ''veterinary medicinal products.'') In accordance with the VICH process, once a final draft of ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports'' 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 applicable 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 will consider its use as a basis for the investigation of adverse event reports that raise questions regarding the purity, safety, potency, or efficacy of veterinary biological products under 9 CFR 116.5. APHIS may also use 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 ''Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports'' 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 22nd day of November 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–30599 Filed 11–30–00; 8:45 am]

BILLING CODE 3410–34–U

DEPARTMENT OF AGRICULTURE

Forest Service

Helena National Forest Travel Plan, Helena National Forest, Broadwater, Lewis and Clark, Meagher and Powell Counties, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare Environmental Impact Statement.

SUMMARY: The Forest Service will prepare an Environmental Impact Statement on a proposal to update travel management and approximately 390,000 acres of National Forest lands on the Townsend, Helena and Lincoln Ranger Districts. These 390,000 acres are the remaining lands that have not been subject to recent motorized travel management decisions or have decisions pending. The project covers three separate areas in the Blackfoot, Divide/Little Blackfoot and the South Belts areas. Motorized travel activities in these areas are presently subject to the June 30, 1994 Helena National Forest Travel Plan.

DATES: Comments concerning the proposal and scope of the analysis

should be received in writing by January 5, 2001.

ADDRESSES: Send written comments to USDA Forest Service, Helena National Forest, 2880 Skyway Drive, Helena, MT 59601.

FOR FURTHER INFORMATION CONTACT: Charlie Hester, Team Leader, (406) 362–4265.

SUPPLEMENTARY INFORMATION: The current Travel Management Plan for the Helena National Forest was approved in June 1994. Since then, site-specific travel management has been completed or is nearing completion on approximately 500,000 acres. These recent efforts have generally prohibited cross-country motorized travel by restricting motorized vehicles, except snowmobiles, to designated routes. These areas are not affected by this proposal.

The remaining areas that do not have recent decisions or decisions pending are the focus of this proposal. The proposal retains current area and route closures and restrictions except where specific changes are identified. The major change proposed is to limit motorized vehicles, except snowmobiles, to designated Forest Development Road and Forest Developmental trails. Designations will specify the classes of vehicles permitted and the authorized period of use.

Motorized use has increased substantially over most areas in the past 10–15 years as off-highway vehicles have become more stable, maneuverable and powerful and riders have become more skilled. This increased use has resulted in the creation of networks of user-created routes often resulting in undesirable impacts to soils, watersheds, vegetation and wildlife resources. Conflicts between motorized and non-motorized users have also become more common and intense. The intent of this proposal is to provide opportunities for motorized activities without duly impacting other forest resources or uses.

The Forest Service is seeking information and scoping comments from Federal, State and local agencies as well as individuals and organizations that may be interested in, or affected by, the proposed action. The Forest Service invites written comments and suggestions related to the proposal. Information received will be used in preparation of the Draft Environmental Impact Statement. For the most effective use, comments should be submitted to the Forest Service within 30 days from the date of publication of the Notice in the **Federal Register**.

The Forest Service expects to release a Draft Environmental Impact Statement in August 2001. A Final Environmental Impact Statement and Record of Decision are expected in April 2002.

The comment period on the Draft Environmental Impact Statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of Draft Environmental Impact Statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. (*Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 553 (1978).) Also, environmental objections that could be raised at the Draft Environmental Impact Statement stage but that are not raised until after completion of the Final Environmental Impact Statement may be waived or dismissed by the courts. (*Wisconsin Heritage, Inc.* v. *Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980).) Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the Final Environmental Impact Statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the Draft Environmental Impact Statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the Draft Environmental Impact Statement or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.).

The responsible official is Thomas J. Clifford, Forest Supervisor, Helena National Forest, 2880 Skyway Drive, Helena, MT 59601.

Thomas J. Clifford,

Helena Forest Supervisor.

[FR Doc. 00–30584 Filed 11–30–00; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

[00–04–A]

Opportunity for Designation in the Fremont (NE), Muncie (IN), and West Lafayette (IN) Areas, and Request for Comments on the Official Agencies Serving These Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration (GIPSA).

ACTION: Notice.

SUMMARY: The designations of the official agencies listed below will end in August 2001. GIPSA is asking persons interested in providing official services in the areas served by these agencies to submit an application for designation. GIPSA is also asking for comments on the services provided by these currently designated agencies:

- East Indiana Grain Inspection, Inc. (East Indiana)
- Fremont Grain Inspection Department, Inc. (Fremont); and
- Titus Grain Inspection, Inc. (Titus).

DATES: Applications and comments must be postmarked or sent by telecopier (FAX) on or before December 31, 2000.

ADDRESSES: Submit applications and comments to USDA, GIPSA, Janet M. Hart, Chief, Review Branch, Compliance Division, STOP 3604, Room 1647–S, 1400 Independence Avenue, SW., Washington, DC 20250–3604; FAX 202–690–2755. If an application is submitted by FAX, GIPSA reserves the right to request an original application. All applications and comments will be made available for public inspection at Room 1647–S, 1400 Independence Avenue, SW., during regular business hours.

FOR FURTHER INFORMATION CONTACT: Janet M. Hart at 202–720–8525, e-mail *janhart@gipsadc.usda.gov.*

SUPPLEMENTARY INFORMATION: This Action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512–1; therefore, the Executive Order and Departmental Regulation do not apply to this Action.

Section 7(f)(1) of the United States Grain Standards Act, as amended (Act), authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services.