Independence Avenue, S.W., Washington, D.C., room 2525–South Building.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record.

Dated: June 17, 1999.

Robert C. Keeney,

Deputy Administrator, Fruit and Vegetable Programs.

[FR Doc. 99–16509 Filed 6–28–99; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[PY–99–005]

United States Grade Standards for Shell Eggs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is soliciting comments on its proposal to change the United States Grade Standards for Shell Eggs. Specifically, AMS proposes to delete the general term ''Inedible eggs'' and its definition, revise the definition of the general term ''Loss'' eggs by including examples of inedible eggs, revise the term descriptive of an A quality white, and delete specifications for packaging materials. These changes would simplify and clarify the terminology used and would remove information that is no longer of value to the industry.

The current United States Grade Standards for Shell Eggs, along with the proposed changes, are available by contacting the address below or by visiting the AMS Internet site at: www.ams.usda.gov/poultry/standards.

DATES: Comments must be received on or before August 30, 1999.

ADDRESSES: Send written comments to Douglas C. Bailey, Chief, Standardization Branch, Poultry Programs, AMS, USDA, Room 3944-South Bldg., STOP 0259, 1400 Independence Avenue, SW, Washington, DC 20250–0259. Comments may also be faxed to (202) 690–0941.

State that your comments refer to Notice number PY–99–005 and include the date and page number of this issue of the **Federal Register**.

Comments received may be inspected at the above location between 8:00 a.m. and 4:30 p.m. Eastern Time, Monday through Friday, except holidays. Comments will also be posted on the Internet at www.ams.usda.gov/poultry/standards.

FOR FURTHER INFORMATION CONTACT: Douglas C. Bailey at (202) 720–3506.

SUPPLEMENTARY INFORMATION: The Agricultural Marketing Act of 1946 (AMA), as amended (7 U.S.C. 1621 *et seq.*) authorizes the establishment of U.S. standards and grades for shell eggs. These standards and grades are maintained by AMS for use as a common language of trade among those buying and selling shell eggs. The standards are used by shell egg processors, wholesale traders, institutions, Federal and State governments, and retailers that sell eggs to the ultimate consumer. AMS also administers a voluntary grading program for shell eggs under the AMA. Any interested person, commercial firm, or government agency can, for a fee, have AMS monitor processing operations and verify that the grade and size of eggs being packaged meet the requirements of the U.S. grade standards and weight classes. Eggs meeting the requirements can be packaged into cartons or other containers bearing the USDA grade shield.

Currently, the definition of ''Loss'' eggs includes inedible eggs. There is also a separate definition for ''Inedible eggs'' that includes examples of such eggs. When applying the grade tolerances of the standard, there is no need to separately identify inedible eggs from loss eggs. Therefore, AMS proposes to delete the general term ''Inedible eggs'' and to add the examples of inedible eggs to the definition of ''Loss'' eggs. This would clarify that eggs with rots, green whites, stuck yolks, blood rings, or free yolk in the white are to be classed as ''Loss'' eggs when applying grade tolerances.

Candling is the process of using light to help determine the quality of an egg. Automated mass scanning equipment is used by most egg packers to detect eggs with cracked shells and interior defects. Hand-candling is done to spot-check and determine accuracy in grading. The breakout method of determining interior quality enables graders and students to calibrate their grading skills against an objective standard. In this method, a micrometer measures the height of the thick white of a broken-out egg and gives a direct reading in Haugh units. Currently, there is a Haugh unit range of ''60 to 72'' for A quality and ''72 or higher'' for AA quality. Because these values appear to overlap, AMS proposes to revise the description for A quality to read ''60 up to, but not including, 72.'' This would clarify the wording and make it consistent with the intent of the description.

Specifications for packaging materials are provided as examples of quality packaging, but do not appear to be of any recognized value to today's industry. Therefore, AMS is proposing to delete this section entirely.

The complete text of the proposed revisions to the grade standards can be obtained from the Internet at www.ams.usda.gov/poultry/standards. A copy can also be obtained by writing to the address above, calling (202) 720–3506, faxing (202) 690–0641, or e-mailing Douglas.Bailey@usda.gov.

Authority: 7 U.S.C. 1621–1627.

Dated: June 23, 1999.

Enrique E. Figueroa,

Administrator, Agricultural Marketing Service.

[FR Doc. 99–16451 Filed 6–28–99; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 99–045–1]

Draft Guideline on Good Clinical Practices, VICH Topic GL9

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are requesting comments on a draft document titled ''Guideline on Good Clinical Practices'' that has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The guideline is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting clinical studies evaluating veterinary products. Because the guideline would apply 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 public input on the draft in the Agency's comments to the VICH Steering Committee.

DATES: To ensure that your comments are considered, we must receive them by August 13, 1999.

ADDRESSES: Please send your comment and three copies to: Docket No. 99–045–1, 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. 99–045–1.

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 on Good Clinical Practices'' by writing to Dr. Lawrence A. Elsken, USDA, APHIS, VS, CVB–LPD, 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/lpd/notices.

FOR FURTHER INFORMATION CONTACT: For information regarding VICH, contact Dr. David A. Espeseth, Special Assistant to the Deputy Administrator, Veterinary Services, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245. For information regarding the draft guideline, contact Dr. Lawrence A. Elsken, USDA, APHIS, VS, CVB–LPD, 510 South 17th Street, Suite 104, Ames, IA 50010; phone (515) 232–5785.

SUPPLEMENTARY INFORMATION: 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 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 biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary medicines and biologics among regulatory agencies in different countries.

The draft document that is the subject of this notice, ''Guideline on Good Clinical Practices'' (VICH Topic GL9), has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to be an international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing, and reporting clinical studies evaluating veterinary products. Because the guideline would apply to veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to prelicensing field studies testing the safety or efficacy of veterinary biological products—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 design and conduct of all field studies testing the safety or efficacy of veterinary biological products in the target species. (The draft guideline refers to such studies as ''clinical studies.'') Once a final draft of ''Guideline on Good Clinical Practices'' has been approved, the guideline will, in accordance with the VICH process, be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents, the guidelines, once finalized, 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 the requirements of applicable regulatory requirements.

Ultimately, APHIS intends to adopt the VICH Steering Committee's final guidance document and publish it for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS intends to use it as a basis for the approval of shipments of veterinary biological products for experimental use under 9 CFR 103.3. APHIS may also use the final guidance document as the basis for proposed additions or amendments to its regulations in 9 CFR subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Given that we anticipate that the applicable provisions of ''Guideline on Good Clinical Practices'' will be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft version of those guidelines.

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

Done in Washington, DC, this 24th day of June 1999.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–16500 Filed 6–28–99; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Farm Service Agency

U.S. Warehouse Act Fees

AGENCY: Farm Service Agency, USDA.

ACTION: Notice.

SUMMARY: This notice publishes a schedule increasing the annual operational fee warehouse operators are charged under the United States Warehouse Act (USWA). This action is needed to increase the amount of revenue generated to recover operational costs projected for operations under the USWA in fiscal year 2000. This notice does not change any of the other various license or inspection fees charged under the USWA.

EFFECTIVE DATE: October 1, 1999.

FOR FURTHER INFORMATION CONTACT: Steve Mikkelsen, Deputy Director, Warehouse and Inventory Division, Farm Service Agency, United States Department of Agriculture, 1400 Independence Avenue, SW, STOP 0553, Washington, DC 20250–0553, telephone (202) 720–2121 FAX: (202) 690–3123, E–Mail: Steve__Mikkelsen@wdc.fsa.usda.gov.