• *Animal identification.* Do you have any suggestions on how to make animal identification practical and useful to stakeholders while simultaneously meeting the needs of animal health officials who must conduct disease tracebacks?

• *Animal tracing.* Do you have any suggestions on how to make the animal tracing component practical, in particular the reporting of animal movements to other premises, while meeting the needs of animal health officials who must conduct disease tracebacks?

During the time that the public meetings were being held, we provided members of the public who were not able to attend a meeting with the option of submitting comments via the Regulations.gov Web site. The last meeting was held on June 30, 2009, and it was our intention to continue to provide the public with the option of submitting written comments for at least 30 days following that final meeting. As noted in the heading **DATES** at the beginning of this notice, we will consider all comments that we receive on or before August 3, 2009.

Done in Washington, DC, this 21st day of July 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9–17797 Filed 7–24–09; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2009–0037]

Determination of Pest-Free Areas in the Republic of South Africa; Request for Comments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that we have received a request from the Government of the Republic of South Africa to recognize 16 additional magisterial districts in 3 provinces as pest-free areas for citrus black spot. After reviewing the documentation submitted in support of this request, the Administrator of the Animal and Plant Health Inspection Service has determined that these areas meet the criteria in our regulations for recognition as pest-free areas. We are making that determination, as well as an evaluation document we have prepared in connection with this action, available for review and comment.

DATES: We will consider all comments we receive on or before September 25, 2009.

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

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0037* to submit or view comments and to view supporting and related materials available electronically.

• *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2009–0037, 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. APHIS–2009–0037.

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: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Phillip B. Grove, Regulatory Coordination Specialist, Regulatory Coordination and Compliance, APHIS, 4700 River Road Unit 156, Riverdale, MD 20737; (301) 734–6280.

SUPPLEMENTARY INFORMATION: Under the regulations in ''Subpart-Fruits and Vegetables'' (7 CFR 319.56 through 319.56–49, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into and spread within the United States.

Section 319.56–4 of the regulations contains a performance-based process for approving the importation of commodities that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the designated phytosanitary measures listed in paragraph (b) of that section. One of the designated phytosanitary measures is that the fruits or vegetables are imported from a pest-free area in the country of origin that meets the requirements of § 319.56–5 for freedom from that pest and are accompanied by a phytosanitary certificate stating that the fruits or vegetables originated in a pest-free area in the country of origin.

Under the regulations in § 319.56–5, APHIS requires that determinations of pest-free areas be made in accordance with the criteria for establishing freedom from pests found in International Standard for Phytosanitary Measures (ISPM) No. 4, ''Requirements for the establishment of pest-free areas.'' The international standard was established by the International Plant Protection Convention of the United Nations' Food and Agriculture Organization and is incorporated by reference in our regulations in 7 CFR 300.5. In addition, APHIS must also approve the survey protocol used to determine and maintain pest-free status, as well as protocols for actions to be performed upon detection of a pest. Pest-free areas are subject to audit by APHIS to verify their status.

APHIS has received a request from the Government of the Republic of South Africa to recognize additional areas of that country as being free of *Guignardia citricarpa,* citrus black spot.[1] Currently, we only allow importation of citrus fruit from the Republic of South Africa when it is grown in the Western Cape Province and the magisterial districts of Hartswater and Warrenton of the Northern Cape Province, which are areas that APHIS has determined to be free of citrus black spot.[2] Specifically, the Government of the Republic of South Africa asked that we recognize the magisterial districts of Boshof, Fauresmith, Jacobsdal, Koffiefontein, and Philippolis in the Free State Province; Christiania and Taung in the North West Province; and Barkly-wes/west, Gordonia, Hay, Herbert, Hopetown, Kenhardt, Kimberely, Namakwaland, and Prieska in the Northern Cape Province as areas that are free of citrus black spot.

In accordance with our regulations and the criteria set out in ISPM No. 4, we have reviewed and approved the survey protocols and other information provided by the Republic of South Africa relative to its system to establish freedom, phytosanitary measures to maintain freedom, and system for the verification of the maintenance of freedom. Because this action concerns the expansion of a currently recognized pest-free area in the Republic of South

[1] A list of pest-free-areas currently recognized by APHIS can be found at *http://www.aphis.usda.gov/import_export/plant/manuals/ports/downloads/DesignatedPestFreeAeas.pdf.*

Africa from which citrus fruit is authorized for importation into the United States, our review of the information presented by the Republic of South Africa in support of its request is examined in a commodity import evaluation document (CIED) titled ''Recognition of Additional Magisterial Districts as Citrus Black Spot Pest-Free Areas for the Republic of South Africa.''

The CIED may be viewed on the Regulations.gov Web site or in our reading room (see **ADDRESSES** above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the CIED by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Therefore, in accordance with § 319.56–5(c), we are announcing the Administrator's determination that the magisterial districts of Boshof, Fauresmith, Jacobsdal, Koffiefontein, and Philippolis in the Free State Province; Christiania and Taung in the North West Province; and Barkly-wes/west, Gordonia, Hay, Herbert, Hopetown, Kenhardt, Kimberely, Namakwaland, and Prieska in the Northern Cape Province meet the criteria of § 319.56–5(a) and (b) with respect to freedom from citrus black spot. After reviewing the comments we receive on this notice, we will announce our decision regarding the status of these areas with respect to their freedom from citrus black spot. If the Administrator's determination remains unchanged, we will add these areas in the Republic of South Africa to the list of pest-free areas.

Done in Washington, DC, this 21st day of July 2009.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E9–17794 Filed 7–24–09; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2009–0056]

Determination of Regulatory Review Period for Purposes of Patent Extension; NAHVAX® Marek's Disease Vaccine

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has determined the regulatory review period for NAHVAX® Marek's Disease Vaccine and is publishing this notice of that determination as required by law. We have made this determination in response to the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that veterinary biologic.

DATES: We will consider all requests for revision of the regulatory review period determination that we receive on or before August 26, 2009. We will consider all due diligence petitions that we receive on or before January 25, 2010.

ADDRESSES: You may submit revision requests and due diligence petitions by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0056* to submit or view revision requests and due diligence petitions and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your request or petition to Docket No. APHIS–2009–0056, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your revision request or due diligence petition refers to Docket No. APHIS–2009–0056.

Reading Room: A copy of the regulatory review period determination and any revision requests or due diligence petitions that we receive on this determination are available for public inspection 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: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Section Leader, Operational Support Section, Center for Veterinary Biologics, Policy Evaluation and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245; fax (301) 734–4314.

For information concerning the regulatory review period determination contact Dr. Patricia L. Foley, Center for Veterinary Biologics, Policy Evaluation and Licensing, VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010; phone (515) 232–5785, fax (515) 232–7120.

SUPPLEMENTARY INFORMATION: The provisions of 35 U.S.C. 156, '' Extension of patent term,'' provide, generally, that a patent for a product may be extended for a period of up to 5 years as long as the patent claims a product that, among other things, was subject to a regulatory review period before its commercial marketing or use. (The term ''product'' is defined in that section as ''a drug product'' [which includes veterinary biological products] or ''any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act.'') A product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

The regulations in 9 CFR part 124, ''Patent Term Restoration'' (referred to below as the regulations), set forth procedures and requirements for the Animal and Plant Health Inspection Service's (APHIS) review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156. As identified in the regulations, the responsibilities of APHIS include:

- Assisting Patent and Trademark Office of the U.S. Department of Commerce in determining eligibility for patent term restoration;
- Determining the length of a product's regulatory review period;
- If petitioned, reviewing and ruling on due diligence challenges to APHIS' regulatory review period determinations; and
- Conducting hearings to review initial APHIS findings on due diligence challenges.

The regulations are designed to be used in conjunction with regulations issued by the Patent and Trademark Office concerning patent term extension, which may be found at 37 CFR 1.710 through 1.791.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For veterinary biologics, the testing phase begins on the date the authorization to prepare an experimental veterinary biologic became effective and runs until the approval phase begins. The approval phase begins on the date an application for a license was initially submitted for approval and ends on the date such license was issued. Although only a portion of a regulatory review period