XV Seminar on Harmonization of Registration and Control of Veterinary Medicines

Americas Committee of Veterinary Medicines (CAMEVET)

Guadalajara, Jalisco, Mexican United States

August 10th - 15th, 2009

According to the activities led by the Americas Committee Veterinary Medicines (CAMEVET) since 1992, the celebration of the present Seminar is proposed, for August 10th to 15th, in the city of Guadalajara, Jalisco, United Mexican States.

As a result of the proposals and conclusions of the previous Seminars, the situation regarding the implementation of the harmonized documents in the countries shall be reviewed, in addition to the participation in the development of worldwide standards, through the chapters relevant to veterinary products of the Terrestrial and Aquatic Animal Health Code of the World Organization for Animal Health (OIE).

Technical subjects shall include the implementation of Good Manufacturing Practices for ectoparasiticides and the stability assessment in veterinary products, as well as the presentation of proposals concerning the registration of nutraceuticals, herbal and homeopathic products, and the guidelines for the registration of biotechnological products

The Seminar shall also include, among other topics, presentations on the application of Good Practices for Distribution and Marketing, related to coding systems, traceability and market products withdrawal, as well as the advances in antimicrobial resistance.

In addition, a meeting of the veterinary industry shall be carried out, open to representatives of the Associations and attending companies, with the purpose of exchanging positions and proposals regarding the activities of the Committee.

Finally, a workshop held by the US Food and Drug Administration and the US Department of Agriculture shall include presentations on the methods applied in the registration of generic products and containing drug combinations, and the setting of withdrawal periods.

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Draft Agenda

Tuesday, August 11th

CAMEVET Opening Session

- Assumption of the Presidency and Vice- Presidency charges
- Seminar opening speeches

Session I – CAMEVET and OIE related activities

- Assessment of the activities carried out by CAMEVET and related to the OIE Terrestrial and Aquatic Animal Health Code.
- Procedures for the participation of CAMEVET on the proposals of creation and modification of the OIE Standards
- OIE Focal Points on Veterinary Medicines
- Review of current discussed topics on OIE and participation alternatives for CAMEVET
- Outcome of the 19th Americas Regional OIE Commission Conference
- State of implementation of CAMEVET harmonized documents in Member countries.
- Relevance and impact of the application of the harmonized document upon Veterinary Products Labeling

Wednesday, August 12th

Session II – Working Papers

- **Good Manufacture Practices for ectoparasiticide veterinary products**
  Presentation of the final document developed by the *ad-hoc* group.

- **Nutraceutical, phytotherapeutical and homeopathic products**
  Presentation of the draft papers developed by the *ad-hoc* groups.

- **Stability assessment in veterinary products**
  Presentation of comments made to the working document

- **Guidelines for the registration of biotechnological products**
  Presentation of the draft paper developed by the Cuban delegation.

Thursday, August 13th

III Session – Technical Presentations

- **Update on antimicrobial resistance**
  Dr. Thomas Shyrock – (Senior Research Advisor - Elanco Animal Health)
- **Procedures applied by EMEA for the adequacy of veterinary products registration systems in new European Union Member Countries**
  (Lecturer to be confirmed)
- **Homologation of productive systems to European Union requirements**
  (Lecturer to be confirmed)
- **Situation, objective and proposal on bovine colostrum replacer/supplement products**
  Dr. Manuel Campos - (The Saskatoon Colostrum Company Ltd. - Canadá)
- **Coding and identification systems for batch numbers, manufacture and expiration dates in veterinary products**
  Milson da Silva Pereira - SINDAN
- **Good Distribution and Commercialization Practices for veterinary products**
  (Lecturers to be confirmed – SINDAN / CLAMEVET)
- **FDA Process for withdrawing an approved new animal drug**
  (Dra. Haydée Fernández – CVM - Food and Drug Administration)

IV Session – Conclusions and recommendations

- Financial status. Presentation of the annual budget.
- Adoption of the proposal for the location of next Seminars
- Conclusions and recommendations. Reading and approval of the final document.

Other activities

Monday, August 10th (Evening)

Plenary session of the veterinary industry

Open meeting for the representatives of Associations and companies participating in the Seminar, with the purpose of sharing positions and proposals related to the activities of the Committee.

Friday, August 14th – Saturday August 15th
Workshop held by U.S: Food and Drug Administration - US Department of Agriculture

Topics to be presented:

- Bioequivalence assessment in veterinary generic products. Registration of generic and combined drugs
- Setting of withdrawal periods.
- Methods applied for the setting of shelf life in veterinary biologicals
- Pharmacovigilance

Venue information
Seminar shall be held at the Expo Guadalajara Convention Center, Mariano Otero No. 1499, Col. Verde Valle, Guadalajara, Jalisco, C.P. 44550, México.
http://www.expo-guadalajara.com/

Translation services (English – Spanish) shall be provided.

Accommodation

The hotel booking can be directly arranged through the Agency **Promotora de Eventos y Viajes SA de CV** for the assistants' convenience. Please find attached the reservation form which includes the hotels list.
The additional service of advice on itineraries and booking of local flights is offered for the participants.

Promotora de Eventos y Viajes SA de CV
Dakota 359 Piso 4 - Col. Nápoles - Del. Benito Juarez. Mexico DF, C.P. 03810
Tel 52 55 5536 9600 / Fax 52 55 55366978
http://www.previsaviajes.com.mx/

Yolanda Buenabad Perez	Gabriela Moreno Sanchez	Lic. Santiago Maciel Arce
Gerente de Reservaciones	Directora de Eventos	Director General
yobuenabad@previsaviajes.com.mx	gabymoreno@previsaviajes.com.mx	smaciel@previsaviajes.com.mx

Registration

Registration fee is 200 US Dollars, to be paid at the beginning of the Seminar.
The registration shall be free of charge for Government representatives.

Pre-registration for the Seminar is recommended. Please confirm your participation by contacting the OIE Regional Representation for the Americas, tel/fax (54-11) 4331-3919/4939/5158/5162/5165, or e-mail to rr.americas@oie.int, with copy to Dr. Martín Minassian, CAMEVET Secretary, secretaria@camevet.org

More information and updates for this Agenda will be also available at the OIE Regional Representation web site.
http://www.rr-americas.oie.int/es/proyectos/es_camevet.htm

Hotel booking is not included in the Seminar registration.

Important – Visas for entering Mexican United States

In order to enter the Mexican United States an entrance permit is required for certain countries, for which it is recommended to visit the National Migration Institute webpage, where the requirements and the description of the procedure are presented.

Requirements for obtaining a visa, migration procedures and list of countries:
http://www.inami.gob.mx/index.php?page/MEN_TRMITES_MIGRATORIOS

Directory of Mexican Embassies:
http://www.sre.gob.mx/acerca/directorio/embajadas/dirembajadas.htm

Directory of Mexican Consular Representations:
http://www.sre.gob.mx/acerca/directorio/consulados/dirconsulados.htm

In case of any contingency during the entrance permit procedure, please contact Dr Salomé Koloffon Tella, from SENASICA International Negotiations Department, salome.koloffon@senasica.gob.mx .

FDA/USDA Workshop

Various Regulatory Aspects of Veterinary Drugs and Biologics

August 14-15, 2009

Draft Agenda

August 14 (Friday):

8:30 – 10:30 **Stability of biologics**
Rick Hill, USDA

- Review of stability concepts and requirements for veterinary biological products in the USA
  - Overview of expiration dating and potency
  - Study design: potency profile
  - Qualitative assays for stability monitoring

10:30 – 11:00 **Break**

11:00 – 12:30 **Registration of generic drugs**
Rosilend Lawson, FDA

- History – Generic Animal Drug and Patent Term Restoration Act (GADPTRA)
- Review/Approval process
- Bioequivalence options
  - *In vivo* blood-level bioequivalence studies
  - Waiver from need to do studies
- Special topics
  - Suitability petitions

12:30 – 14:00 **Lunch**

14:00 – 16:00 **Determination of withdrawal times**
Lynn Friedlander, FDA

- Why do we assign withdrawal times
- What are the elements of a well-conducted depletion study
- Examples of depletion study data and the interpretation of those data to assign a withdrawal time
- Special considerations for injection site residues
- Special considerations for milk residues

16:00 – 17:00 **Discussion with attendees**

August 15 (Saturday):

8:30 – 10:30 **Pharmacovigilance**
John Baker, FDA

- History
- Professional review staff and workload
- ADE review process
- Use of the data
- Communication of findings
- Future goals and program developments

10:30 – 11:00 **Break**

11:00 – 12:00 **Combination drugs**
Haydée Fernández, FDA

- Historical perspective
- Approval of combination drugs composed by approved individual components (ADAA law)
- Current thinking and discussions on the approval of non-ADAA drugs (at least one ingredient is new)

12:00 – 13:00 **Closure and distribution of certificates**