



PRELIMINARY AGENDA

**X SEMINAR ON HARMONIZATION OF REGISTER AND CONTROL OF
VETERINARY MEDICINES
COMMITTEE OF THE AMERICAS OF VETERINARY MEDICINES (CAMEVET)
BRASILIA, BRAZIL 9-12 AUGUST 2004**

**CVM/FDA WORKSHOP ON “FDA APPROACH TO THE HUMAN FOOD
SAFETY EVALUATION OF VETERINARY DRUGS”
BRASILIA, BRAZIL, 12-14 AUGUST 2004**

As a continuance of harmonization activities carried out by the Regional Representation for the Americas/CAMEVET since 1992 and based on agreements derived from the IX Seminar, the X Seminar on Harmonization of the Register and Control of Veterinary Medicines will be held in Brasilia, Brazil on 9-11 August 2004.

In this opportunity, the official and private sector will review the past IX Seminars aiming ratification or modification of harmonization-setting during the Seminars. Additionally discussions will take place on the institutionalization of offices in charged of biological and pharmacological register in the OIE American country members.

After the X Seminar and in the same conference room, on 12-14 August, the CVM/FDA, and as well as in the IX Seminar, will develop a workshop on the “FDA Approach to the Human Food Safety Evaluation of Veterinary Drugs”. The objective of this Workshop is to review to the regulation of veterinary drug residues present in human food. The workshop will also familiarize the participants with the interpretation and analysis of toxicological and residue data presented by pharmaceutical sponsors for the human food safety evaluation of veterinary drugs. At the end of the Workshop, participants will compare the FDA approach with the process used by JECFA and FAO for the determination of MRL’s.

**AGENDA X SEMINAR ON HARMONIZATION OF REGISTER AND CONTROL
OF VETERINARY MEDICINES**

MONDAY AUGUST 9TH

- 8:00 - 9:00 Participants Registration
- 9:00-9:30 Opening Session. CAMEVET's President and Vice-President Assumption
- 9:30-9:45 Address by Minister of Agriculture, Livestock and Suppliers from Brazil
Dr. Roberto Rodríguez
- 09:45-10:00 Address by the OIE Regional Representation for the Americas
- 10:00-10:15 Review by the Official Sector of Last CAMEVET'S Seminars. Past, Present
and Future: Achievements and Challenges.
Official Sector Representatives
- 10:15-10:30 Review by the Industry on Last CAMEVET's Seminars.
- 10:30-11:00 Coffee Break
- 11:00-11:30 Discussion on the Presentation of the Official and Private Sector on
CAMEVET's Seminars
- 11:30-12:30 Harmonization of Pharmacological Products Technical Guidelines Selected
During IX Seminar (see list attached)
- Lunch
- 2:30-4:30 Follow up of Harmonization of Pharmacological Products Technical
Guidelines Selected During IX Seminar (see list attached)
- 4:30-5:00 Coffee Break
- 5:00-6:00 Follow up of Harmonization of Pharmacological Products Technical
Guidelines Selected During IX Seminar (see list attached)

TUESDAY AUGUST 10TH

- 9:00-10:30 Harmonization of Biologics Technical Guidelines Selected During IX
Seminar (see list attached)

- 10:30-11:00 Coffee Break
- 11:00-12:00 Follow up Harmonization of Biologics Technical Guidelines Selected During IX Seminar. (see list attached)
- Lunch
- 2:30-3:00 Discussion on Presentation by Delegation of Cuba on Clinical Tests, Phase III
- 3:00-4:00 Model of Pharmacological Products and Biologic Registration Form.
Dr. Enrique Argento (CAPROVE)
- 4:00-4:30 Coffee Break
- 4:30-6:00 Discussion on Labeling Harmonization. Presentation by (Chamber of Veterinary Products of Brazil) SINDAN

WEDNESDAY AUGUST 11TH

- 9:00-9:30 Safety Procedures for Food-Producing Animals.
Dr. Francisco Pereyra de Lucena. Ministry of Agriculture, Brazil
- 9:30-10:30 Report on the on GMP Course hold in Uruguay.
Discussion on Glossary
Dr. Elia Muñoz . (DILAVE) Uruguay
- 10:30-11:00 Coffee Break
- 11:00-12:00 Review of Document Presented by Mexico: “Classification of veterinary medicines and level of trade risk”
- 12:00-12:30 Risk Analysis applying methodology”
Dr. Jacques Acar. Eli Lilly
- Lunch
- 2:30-3:00 VICH activities relating to FDA
Dr. Lous T. Mulligan
VICH activities VICH relating USDA/APHIS
Dr. Frana
Report on 14th VICH Steering Committee Meeting , hold in Tokyo, Japan

- 3:00-4:00 Identification and follow up system of approved CAMEVET's Recommendations
Dr. Adela Encinosa Liñero. Cuba
- 4:00-5:00 Recognition System of Clinical Test Results for Veterinary Medicines Register
Dr. Florestan Maliandi
- 5:00-6:00 Creation of an Ad-hoc Committee to Solve Discrepancies and Answer Consultations on Implementation and Interpretation of CAMEVET's Recommendations
Dr. Enrique Argento (CAPROVE)

THURSDAY AUGUST 12TH

- 9:00-9:30 Report on CAMEVET's Forum
Regional Representation for the Americas
- 9:30-10:00 CAMEVET'S financial Report
- 10:00-10:30 Coffee Break
- 10:30-11:00 Conclusions and Recommendations

LIST OF BIOLOGICS AND PHARMACOLOGICS TO HARMONIZE (text in Spanish)

Productos Biológicos:	
Vacunas a virus vivos	DVB PI3 BOVINA PARAINFLUENZA CANINA CALICIVIROSI FELINA ADENOVIRUS TIPO 2 CANINO ENCEFALOMIELITIS AVIAR
Vacunas a virus inactivados:	CORONAVIRUS BOVINO EDS AVIAR ARTRITIS VIRAL VIRUELA AVIAR HCI

Bacterinas	ESCHERICHIA COLI (Bov – Porc) FOOT ROOT (NODOSUS) ADENITIS EQUINA VIBRIOSIS EPIDIDIMITIS OVINA ANTIMASTITIS ERISPELOSI PAVOS
Organismos Genéticamente Modificados	CONTRA Boophilus microplus MAREK GENETICAMENTE MOD. GUMBORO GENETICAMENTE MOD.
Productos Farmacológicos	
Antiparasitarios Internos	DIPROPIONATO DE IMIDOCARB NITROXINIL
Antiparasitarios Externos	CLORPIRIFÓS CIROMAZINA CARBARIL FIPRONIL
Anticoccidiales	NICARBACINA MADURAMICINA MONENSINA AMPROLIO
Antimicrobianos	AMPICILINA ÁCIDO CLAVULÁNICO GRISEOFULVINA RIFAMPICINA RIFAMIXINA TIAMULINA
Desinfectantes	AMONIOS CUATERNARIOS CLORHEXIDINA CLORURO DE BENZALCONIO CLORURO DE BENCETONIO CLORURO DE CETRIMONIO
Vitaminas	HIDROSOLUBLES
Promotores de Crecimiento	ZERANOL TRENBOLONA
Antiinflamatorios	FENILBUTAZONA DICLOFENAC KETOPROFENO
Antihistamínicos	DIFENILHIDRAMINA
Antidiarreicos	BENCETIMIDA
Anestésicos locales	BENZOCAINA
Tranquilizantes	AZAPERONA BENZODIACEPINAS
Carminativos	SIMETICONA
Hormonales	TESTOSTERONA BENZOATO DE ESTRADIOL

	PROGESTERONA
Estimulante Central	CAFEINA

**AGENDA FOR THE FDA WORKSHOP ON THE HUMAN FOOD SAFETY
REGULATION OF VETERINARY DRUGS**

THURSDAY AUGUST 12th

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|------|---|----------------|
| 1:00 | Good Laboratory Practices/Laboratory Animal Care | T. Mulligan |
| 1:45 | Safety of antimicrobial drugs in food-producing animals | H. Fernández |
| 2:30 | Review of laboratory animal toxicology data | T. Mulligan |
| 3:15 | Break | |
| 3:45 | Review of laboratory animal toxicology data | H. Fernández |
| 4:30 | Determination of MRLs and withdrawal times | L. Friedlander |
| 5:30 | Adjourn | |

FRIDAY AUGUST 13TH

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|-------|---|----------|
| 9:00 | Analytical methods and validation to support MRLs. | R. Ellis |
| 10:00 | Attendees divided into 4 groups to review data on 4 different drugs | |
| 10:30 | Groups 1 & 2: review of toxicology data on Ivermectin and Oxytetracycline
Groups 3 & 4: review of toxicology data on Diclazuril and Carbadox | |
| 12:00 | Lunch | |
| 1:00 | Groups 1 & 2: review of residue chemistry data and analytical methods on Ivermectin and Oxytetracycline
Groups 3 & 4: review of residue chemistry data and analytical methods on Diclazuril and Carbadox | |
| 2:30 | Groups 1 & 2: review of toxicology data on Oxytetracycline and Ivermectin
Groups 3 & 4: review of toxicology data on Carbadox and Diclazuril | |
| 4:00 | Groups 1 & 2: review of residue chemistry data and analytical methods on Oxytetracycline and Ivermectin
Groups 3 & 4: review of residue chemistry data and analytical methods on Carbadox and Diclazuril | |

Time	Group	Drug	Topic
8/13 10:30 – 12:00	1	Ivermectin	Toxicology
	2	Oxytetracycline	Toxicology
	3	Diclazuril	Toxicology
	4	Carbadox	Toxicology
8/13 1:00 – 2:30	1	Ivermectin	Residue
	2	Oxytetracycline	Residue

	3	Diclazuril	Residue
	4	Carbadox	Residue
8/13 2:30 – 4:00	1	Oxytetracycline	Toxicology
	2	Ivermectin	Toxicology
	3	Carbadox	Toxicology
	4	Diclazuril	Toxicology
8/13 4:00 – 5:30	1	Oxytetracycline	Residue
	2	Ivermectin	Residue
	3	Carbadox	Residue
	4	Diclazuril	Residue

SATURDAY AUGUST 14TH:

9:00	Group 1: discussion of Ivermectin	Group 1
9:30	CVM and JECFA decisions: comparison	FDA
9:45	Group 2: discussion of Oxytetracycline	Group 2
10:15	CVM and JECFA decisions: comparison	FDA
10:30	Break	
11:00	Group 3: discussion of Diclazuril	Group 3
11:30	CVM and JECFA decisions: comparison	FDA
11:45	Group 4: discussion of Carbadox	Group 4
12:15	CVM and JECFA decisions: comparison	FDA
12:30	Workshop Evaluation	
1:00	Adjourn	

THE HARMONIZATION SEMINAR AND THE FDA WORKSHOP WILL HAVE SIMULTANEOUS TRANSLATION

SEMINAR FEE: USD 200.- per person (Private Sector only)

REGISTRATIONS SHOULD BE MADE ACCESING : www.sindan.com.br

VENUE OF THE EVENTS

**HOTEL BLUE TREE PARK BRASILIA
SHTN. Trecho 01, Con. 1B, Bloco C
Brasilia DF
Tel: (55-61) 424-7000
Fax (55-61) 424-7001**

sitio web: www.bkuetree.com.br

Accommodation fees:

Single room: \$R 180* plus tourism tax per day \$R 1,50

Double room: \$R 220 * plus tourism tax per day \$R 1,50

- **includes breakfast**

HOTEL RESERVATIONS SHALL BE MADE, MENTIONING THE OIE, TO THE TOURISM ENTERPRISE: FOUR POINTS, Attn: Fatima Teixeira, TEL: (55-11) 6193-8612 OR E-MAIL fatima@fourpoints.com.br