

METHODS COMMITTEE REPORTS

Committee on Drugs and Related Topics

MARY C. CARSON, CHAIR

U.S. Food and Drug Administration, Center for Veterinary Medicine, 8401 Muirkirk Rd, Laurel, MD 20708

LEENDERT A. VAN GINKEL, IMMEDIATE PAST CHAIR

National Institute of Public Health and the Environment, PO Box 1, 3720 AB Bilthoven, The Netherlands

CLYDE NORA CARDUCCI, SECRETARY

Facultad de Farmacia y Bioquímica, Universidad de Buenos Aires, Buenos Aires, Argentina

THOMAS P. LAYLOFF

Management Sciences for Health, #5 Thomas Ct, PO Box 286, Granite City, IL 62040

DAVID J. MAZZO

Chugai Pharma USA LLC, 6275 Nancy Ridge Dr, San Diego, CA 92121

MOHAMMED MUSHTAQ

Drug Safety and Metabolism-Animal Health, Schering-Plough Research Institute, 144 Route 94 South, PO Box 32, Lafayette, NJ 07848

LINDA NG

U.S. Food and Drug Administration, Center for Drug Evaluation and Research, HFD-550, 5600 Fishers Ln, Rockville, MD 20857

VALERIE B. REEVES

U.S. Food and Drug Administration, Center for Veterinary Medicine, 7500 Standish Pl, Rockville, MD 20855

SUMIT SEN

U.S. Food and Drug Administration, Office of Regulatory Affairs, Pacific Regional Laboratory SW, 1521 West Pico Blvd, Los Angeles, CA 90015

GEORGE F. PETERSON, SAFETY ADVISOR

Alcohol and Tobacco Tax and Trade Bureau, Alcohol Lab, 355 N. Wiget Ln, Walnut Creek, CA 94598

FOSTER McCLURE, STATISTICAL ADVISOR

U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy, College Park, MD 20740

Committee Actions

The Committee hosted a half-day symposium at the 119th Annual Meeting on Pharmaceutical Authenticity and Safety. This Committee has no methods active in the collaborative study process. There are numerous topics open and the Committee remains active.

(1) The Committee voted to recommend Method **2003.04**, *Determination of Clopidol in Chicken Tissues*, for Final Action.

(2) The Committee voted to recommend that *Official Method 961.23, ANOT Residues in Animal Tissues*, should be left in the OMA as is, but with a note added: "At the time of review in 2005, the reference standard was not commercially available."

(3) The Committee accepted the Drug Residues in Foods Report, GR Joe Boison, with modifications. The Committee concurred with his recommendation of appointing Topic Advisors for *Evaluation of Rapid Tests for Screening Drug Residues in Animal Tissues and Biological Fluids*, *Nitrofurans in Foods*, *Malachite Green in Fish*, and *Biosensors in Drug Residue Analysis*. The Committee is seeking volunteers to serve in these positions.

(4) The Committee accepted the Drugs report, GR Maria Inés Cereijo¹, Justesa Imagen Argentina S.A, Viamonte 1328, Buenos Aires, A1052ACB, Argentina, E-mail: icereijo@ciudad.com.ar. The Committee noted that the GR is currently acting as a Topic Advisor for Enalapril Maleate, and recommended that she be appointed as the Topic Advisor. The Committee further recommended that Committee member Tom Layloff serve in the role of GR for this topic.

(5) Stephen Sherken, U.S. Food and Drug Administration, retired, was appointed by Foster McClure to replace McClure as the Statistics Advisor.

Cosmetics, David Prantis

The GR did not report activity this past year.

Drug Residues in Foods, Joe Boison

General Referee Joe O. Boison, Canadian Food Inspection Agency, CFIA Saskatoon Laboratory, Centre For Veterinary Drug Residues, 116 Veterinary Rd, Saskatoon, SK, Canada S7N 2R3, Tel: 306-975-5358, Fax: 306-975-5711, E-mail: jboison@inspection.gc.ca

2003.04 *Determination of Clopidol in Chicken Tissues*: Study Director Guo-Fang Pang, Qinquangdao Entry-Exit Inspection and Quarantine Bureau of P.R. China, No. 39 Haibin Rd, Qinquangdao 06600-2, People's Republic of China, Tel/Fax: 86-335-340-7608, E-mail: gfpang@heinfo.cn. Study completed and granted Official First Action in 2003. Manuscript has been published

¹ Inés Cereijo, General Referee of Drugs and Related Topics, passed away on March 29, 2006.

(*J. AOAC Int.* (2003) **86**, 685–693). Recommend adoption for Final Action. Continue study.

Boison reviewed Chapter 23 of the *Official Methods of Analysis*, Drugs and Feed Additives in Animal Tissues, submitted by William Horwitz, and made the following recommendations: (1) The document was to be published as is with the following exception: Official Method **961.23**, *ANOT Residues in Animal Tissues*: ANOT (3-Amino-5-nitro-*o*-toluamide) requires the use of analytical standard previously available from Dow Chemical Co. Dow does not manufacture this standard any longer, and he failed to find an alternative supplier/manufacturer for this standard. In the absence of an authentic standard for the analysis, he recommended to the Editorial Board that the method be deleted from the OMA.

Recommendations

(1) *Evaluation of Rapid Tests for Screening Drug Residues in Animal Tissues and Biological Fluids*: Establishment of new topic and appointment of a Topic Advisor is recommended.

(2) *Nitrofurans in Foods*: Establishment of new topic and appointment of Topic Advisor is recommended.

(3) *Malachite Green in Fish*: Establishment of new topic and appointment of Topic Advisor is recommended.

(4) *Biosensors in Drug Residues Analysis*: Establishment of new topic and appointment of a Topic Advisor is recommended.

Drugs, Maria Inés Cereijo

General Referee Inés Cereijo. The GR report contains a summary of comments about: (1) *OMA Review*: Cereijo

reviewed chapters 18–22 of the OMA, Drugs (sent to her by Horwitz). She updated several references.

(2) *Symposium on Pharmaceutical Authenticity and Safety*: September 12 at the 119th Annual Meeting. It aimed at improving critical points in the pharmaceutical analysis field, such as traceability assessment, use of appropriate reference materials, and proficiency testing implementation. Recognized experts participated. Other important and complementary topics such as the applicability of advanced technologies to reach the highest quality results and sampling were also presented. The co-chairs were Inés Cereijo, Clyde Carducci, and Irma Ercolano (National Institute of Medicines, Argentina).

Interlaboratory Studies

A report about the development and results of a Program of Proficiency Testing for the pharmaceutical industry in Argentina, comprised of a group of AOAC members together with the National Institute of Medicines, is described. This program aims that pharmaceutical QC laboratories reach the highest quality in their performance and also intends to lead the accreditation of the participants according to their *z*-score values. From the third round of the program, 6 new CRMs with their assigned value and uncertainties were obtained: amiodarone hydrochloride, salbutamol sulfate, amlodipine besylate, ciprofloxacin hydrochloride, neomycin sulfate, and polymixin B sulfate. Round 4 is now in preparation.

Determination of Maleate Enalapril by HPLC: Topic Advisor Clyde Carducci. The precollaborative study is being evaluated by the Topic Advisor. Continue study.