

5100 Paint Branch Parkway
College Park, MD 20740-3835

M-I-09-6

October 16, 2009

TO: All Regional Food and Drug Directors
Attn: Regional Milk Specialists

FROM: Dairy and Egg Branch (HFS-316)

SUBJECT: Addition of a Claim for Water Buffalo Milk to the Charm SL Beta-lactam Test Kit, DSM Delvotest P and the DSM Delvotest SP Test Kits

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) has evaluated data supporting the use of the Charm SL Beta-lactam Test Kit, DSM Delvotest P and the DSM Delvotest SP Test Kits for testing raw, commingled water buffalo milk under the National Conference on Interstate Milk Shippers (NCIMS) Grade "A" Milk Safety Program.

The FDA evaluation of the data, presented by the State of Vermont's Department of Agriculture, indicates that the performance of these three (3) test kits meet the standards established to determine the acceptance of a test kit for use in raw, commingled water buffalo milk. The acceptance of these three (3) test kits for raw, commingled water buffalo milk represents a claim for amoxicillin, ampicillin, certiofur, cephalirin, and penicillin G for the Charm SL Beta-lactam Test Kit and amoxicillin, ampicillin, cephalirin, and penicillin G for the DSM Delvotest P and the DSM Delvotest SP Test Kits. These data have been evaluated in accordance with the standards established for the acceptance of screening tests for monitoring raw, commingled milk in accordance with the provisions of Appendix "N" of the Grade "A" Pasteurized Milk Ordinance (PMO).

The NCIMS Executive Board at the 2009 NCIMS Conference in Orlando, FL accepted the use of these test kits when used as labeled (Proposal 219). Following is the memorandum of acceptance from FDA's CVM.

An electronic version of this coded memorandum is available for distribution to Regional Milk Specialists, State Milk Regulatory Agencies, State Laboratory Evaluation Officers and State Milk Sanitation Rating Officers in your region. The electronic version should be widely distributed to State Veterinarians, State Veterinary and Pharmacy Boards, Veterinarian Professional Organizations, representatives of the dairy industry and other

interested parties and will also be available on the FDA Web Site at <http://www.fda.gov> at a later date.

If you would like an electronic version of this document prior to it being available on the FDA Web Site, please e-mail your request to Robert.Hennes@fda.hhs.gov.

A handwritten signature in black ink, appearing to read "Robert Hennes", is centered on a white rectangular background.

Robert F. Hennes, RS, MPH
CAPT, US Public Health Service
Dairy and Egg Branch

Attachment: CVM Memo-“Addition of a Claim for water Buffalo Milk to the Charm SL Beta-lactam Test Kit, DSM Delvotest P and the DSM Delvotest SP Test Kits”, October 9, 2009



Center for Veterinary Medicine
Office of Research

Food and Drug Administration
8401 Muirkirk Road
Laurel MD 20708

Memorandum

Date: October 9, 2009

From: Philip James Kijak, Ph.D.

Subject: Addition of a Claim for Water Buffalo Milk to the Charm SL Beta-Lactam Test Kit, DSM Delvotest P and the DSM Delvotest SP Test Kits

To: Robert F. Hennes, Milk Safety Team

An evaluation of the Charm Sciences, Inc. SL Beta-Lactam test kit, the DSM Delvotest P and the DSM Delvotest SP test kits for use with Water Buffalo milk has been completed. The study was coordinated by the State of Vermont Department of Agriculture Food and Markets. The testing was conducted by the State of Vermont and at two independent laboratories. Star Hill Farms, Woodstock, Vermont, provided both the control buffalo milk and the incurred buffalo milk (milk from animals treated with the drug). The test kit manufacturers provided the test kits. The protocol for the study was reviewed and approved by CVM. The testing protocol was based on the CVM "PROTOCOL FOR EVALUATION OF MILK RESIDUE SCREENING TESTS WITH GOAT MILK."

The testing was done in three groups, with 60 control samples in each group. An additional set of 60 control samples was assayed during a repeated experiment. For all sets of 60 control samples tested, no false positive responses were observed. For the incurred samples, the protocol was modified using only one animal that was dosed for each of the five drugs. This change was allowed because reducing the number of animals used for incurred milk would not compromise the validity of the test kit evaluation and it still met the requirements of the protocol for bovine milk where only single animal incurred samples are used for the evaluation of the test kit. Samples of water buffalo milk were taken at 12 hour intervals and tested using the BSDA and the relevant test kits. Samples were collected from the animals until both test kits gave negative results. The test kits gave acceptable results with incurred water buffalo milk.

Based on the data generated, it is recommended that the Charm SL Beta-Lactam test kit for Amoxicillin, Ampicillin, Ceftiofur, Cephapirin and Penicillin G, and the DSM Delvotest P and DSM Delvotest SP test kits for Amoxicillin, Ampicillin, Cephapirin and Penicillin G are suitable for testing raw commingled water buffalo milk. The performance of the test kits for testing water buffalo milk was similar to the performance of the test kits for testing bovine milk.

Philip James Kijak, Ph.D.
Acting Director, Division of Residue Chemistry
CVM Office of Research

David G. White, Ph.D., Director, CVM Office of Research:

Concur Do not Concur

cc: CFSAN/LPET