



June 6, 2011

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 11-14

**United States
Department of
Agriculture**

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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TO: Biologics Licensees, Permittees, and Applicants
Directors, Center for Veterinary Biologics
Veterinary Services Management Team
Area Veterinarians in Charge
State Veterinarians

FROM: Richard E. Hill, Jr. /s/ *Richard E. Hill, Jr.*
Director
Center for Veterinary Biologics

SUBJECT: Use of Symbols on Labeling for Diagnostic Test Kits

I. PURPOSE

This Notice describes symbols that may be used on labeling for diagnostic test kits.

II. BACKGROUND

Requirements for the information that must be included on final container labels, carton labels, and product enclosures are specified in Title 9, Code of Federal Regulations (9 CFR), Part 112.2. This regulation does not address the use of symbols, rather than text, in the labeling.

III. POLICY

The Center for Veterinary Biologics will allow the use of specific internationally recognized symbols for the labeling of diagnostic test kits in situations where the use of text is not practical. When these symbols are used, an explanatory key must be included in the product enclosure. For multi-language labels, the explanatory key must include all languages that are used in the labeling. The following symbols may be used:

Symbol	Used for	Reference
	Use by (expiration date)	9 CFR 112.2(a)(9)(i)
	Batch code (component Lot Number)	VSM* 800.73, Section V

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Symbol	Used for	Reference
	Serial number	9 CFR 112.2(a)(9)(iv)
	Authorized representative in the European Community (European distributor)	9 CFR 112.4(c)
	Manufacturer (name and address of licensee and subsidiary or permittee and foreign producer)	9 CFR 112.2(a)(2)
	Date of manufacture (fill date)	
	Temperature limitation (storage temperature range)	9 CFR 112.(a)(4)
	Upper limit of temperature	
	Lower limit of temperature	
	Consult instructions for use	9 CFR 112.2(a)(5)
	<i>In vitro</i> diagnostic medical device	
	Positive control	
	Negative control	
	Catalog number	
	Caution, consult accompanying documents	9 CFR 112.2(a)(5)
	Keep dry	
	Keep away from sunlight	
	This side up	

*Veterinary Services Memorandum

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IV. IMPLEMENTATION/ APPLICABILITY

This change is applicable to the labeling of diagnostic test kits only, and is effective June 6, 2011.