



**Pennsylvania Department of
AGRICULTURE
Bureau of Food Safety and Laboratory Services**

SUPERSEDES AND RESCINDS PRIOR STANDARDS DATED OCTOBER 22, 2007

Date: January 17, 2008

Subject: Revised Standards and Procedure for the Approval of Proposed Labeling of Fluid Milk

To: All Fluid Milk Permit Holders

From: William Chirdon, Director, Bureau of Food Safety and Laboratory Services.

I. Introduction

7 Pa. Code § 59.21(d) requires that labeling of all milk be submitted to the Department for approval. Compliance with this requirement of the law has not been uniform. In an effort to gauge compliance, in August 2007 the Department (“PDA”) requested from all fluid milk processors copies of all fluid milk retail labels in use in the Commonwealth of Pennsylvania. The request enabled the Department to better fulfill its regulatory duties, beginning with fluid milk labeling. As a result, the Department is clarifying and standardizing the label approval process for fluid milk.

Commencing on March 1, 2008, all new proposed fluid milk labels for which approval is sought will be reviewed in the fashion and according to the guidelines set forth herein.

II. Standards and Procedure for the Approval of Proposed Labeling - Fluid Milk

- The Pennsylvania Department of Agriculture (PDA) is charged with enforcement of the Food Act, the Milk Sanitation Law and the regulations attendant to each.¹
- The Food Act prohibits the sale of food that is “misbranded.”²
- Food is “misbranded” if its labeling is false or misleading in any way.³
- The regulations promulgated under authority of the Milk Sanitation Law prohibit misleading words or endorsements on milk-labels.⁴
- PDA believes that the person who labels food for sale must be responsible to ensure that label statements are true and accurate, and are not false or misleading in any way.

¹ The Food Act, at 31 P.S. § 20.13(a), and the Milk Sanitation Law, at 31 P.S. § 645 *et seq.*

² 31 P.S. § 20.3(2).

³ 31 P.S. § 20.9(a)(1).

⁴ 7 Pa. Code § 59.21(g).

- The regulations promulgated under authority of the Milk Sanitation Law require that proposed labeling for all containers and closures for milk be submitted to PDA for approval.⁵

In consideration of the foregoing, PDA hereby provides notice of the manner in which it shall apply and exercise its administrative discretion in determining whether a milk label is “misleading,” and therefore a “misbranded” food that may not be lawfully sold.

1. Reviewing current and proposed milk labels. The holder of a permit issued under authority of the Milk Sanitation Law shall, before using a fluid milk label in commerce, apply for the approval of PDA for the use of that label.

(A) Fluid Milk labeling in use as of the date of issuance of these standards that PDA has previously approved need not be resubmitted for approval.

(B) Fluid Milk labeling in use as of the date of issuance of these standards that PDA has previously disapproved through a Proposed Adjudication issued in October 2007 will be handled as follows: Such Proposed Adjudications issued in October 2007 will be withdrawn by separate notification to the recipients simultaneous herewith. Such labeling is not approved by virtue of any such withdrawal and such labeling will be considered to be pending before PDA for approval. Separate communication will be forthcoming to each such permit holder requesting whether they intend to revise such label, or seek approval of the label without revision in accordance with the standards set forth herein. If the intent is to revise such a label, it shall be submitted in accordance with Section 1 (C) below. If approval will be sought of the label without revision, proof of compliance with the requirements of Section 7(B)i.5 will be requested. If disapproved in accordance with the standards set forth herein, notification shall be issued by PDA on or before March 1, 2008 directing that use of the label shall be discontinued no later than July 1, 2008. If approved in accordance with the standards set forth herein, an approval will be issued on or before March 1, 2008.

(C) Fluid Milk Labeling which has not been approved or submitted to PDA for approval before the date of issuance of these standards, but which is currently in use or first used within 60 days of the issuance of these standards, shall be submitted to PDA for approval by March 1, 2008 and may continue to be used while review is pending. If disapproved, the notification shall direct that such labeling shall be discontinued within four months of such disapproval.

2. Application required. A permit holder seeking PDA’s approval of milk labeling shall apply to PDA for approval to the following address:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
ATTN: Milk Sanitation Division
2301 North Cameron Street
Harrisburg, PA 17110-9408

3. Form. The applicant may use an application form that PDA will provide upon request, or may apply by letter requesting label approval. The application shall include clear, accurate copies of labels for which approval is sought, as well as all other materials the label proponent wishes the Department to consider in order to substantiate any claims on the label.

⁵ 7 Pa. Code § 59.21(d).

4. Standard. The Department shall approve the use of a label if it meets the requirements of the Milk Sanitation Law, the Food Act and their respective attendant regulations, and shall apply the criteria described in this document in exercising its administrative discretion.

5. Approval or denial. PDA shall, within 30 business days of receiving a complete application, mail the applicant its written approval or denial of the application.

(A) If the application is denied, the written denial shall set forth the basis for denial, and afford the applicant notice and opportunity for an administrative hearing on the denial.

(B) If the application is granted, the written approval shall contain a copy of the label and assign a unique serial number to the label approved under the application. PDA shall retain copies of these approvals.

6. Subsequent changes of an approved label. If a label has been approved by PDA, the colors and graphics may be changed without requiring re-approval of the label, provided such changes otherwise comply with this document. If the text, type size or wording is to be changed, the label must be submitted to PDA for approval.

7. Label Representations.

(A) No labeling may be false or misleading. In determining whether labeling is misleading there shall be taken into account (among other things) not only representations made but also the extent to which the labeling fails to reveal facts that are material in light of such representations.

i. In no instance shall any label state or imply that milk from cows not treated with recombinant bovine somatotropin (rBST, rbST, RBST or rbst) differs in composition from milk or products made with milk from treated cows, or that rBST is not contained in or added to the product. If a product is represented as, or intended to be represented to consumers as, containing or produced from milk from cows not treated with rBST any labeling information must convey only a difference in farming practices or dairy herd management methods.

ii. No labeling may contain references such as “No Hormones,” “Hormone Free,” “Free of Hormones,” “No BST,” “Free of BST,” “BST Free,” “No added BST,” or any statement which indicates, implies or could be construed to mean that no natural bovine somatotropin (BST) or synthetic bovine somatotropin (rBST) are contained in or added to the product. Preceding any of these phrases with the words, “Farmers Pledge” or an equivalent does not render any such statement free of the implication that it indicates, implies or could be construed to mean that no natural or synthetic bovine somatotropin are contained in or added to the product.

iii. References such as “No rBST,” “rBST Free,” “Free of rBST,” “No added rBST” may be considered misleading labeling based upon the entirety of the particular label under review. By way of guidance, a label containing such references may be approved if such references are part of language defined in paragraph 7(B) as a “Claim,” and is accompanied as set forth in paragraph 7(B) by a “Disclaimer.” An example of such a Claim and Disclaimer would be “No rBST was used on cows producing this milk. No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows.” In such cases, the reference “No rBST,” or the other references listed above, may be accentuated by different type style or size but not more than twice the size of the other

language in the Claim and Disclaimer. Any use of the reference “No rBST,” or the other references listed above, must not imply that rBST is not contained in or added to the product or that milk, or products made with milk, from cows not treated with rBST differs in composition from milk or products made with milk from treated cows.

iv. Whenever used in 7(A) of this document, the term rBST shall also include the terms rBGH, growth hormone, bovine growth hormone, artificial growth hormone, artificial bovine growth hormone, synthetic growth hormone, synthetic bovine growth hormone or any other term intended to designate recombinant bovine somatotropin.

(B) Permitted Claims. The following claims are permitted:

i. **RBST.**⁶ If the product is represented as, or intended to be represented to consumers as, containing or produced from milk from cows not treated with rBST:

1. “From cows not treated with rBST. No significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows” or a substantial equivalent. Hereinafter, the first sentence shall be referred to as the “Claim,” and the second sentence shall be referred to as the “Disclaimer.”

- a. A substantial equivalent Claim would include, for example: “Produced without the use of rBST” instead of “From cows not treated with rBST.”
- b. The phrase “Farmer’s Pledge” may precede any such Claim, provided that what follows clearly articulates a difference in farming practices or dairy herd management methods and does not state or imply a compositional difference between milk from rBST-treated and non-rBST treated cows. An example of a permissible pledge would be “Our farmers pledge not to use rBST.”
- c. Wherever used in 7(B), the term rBST shall also include the terms rBGH, artificial bovine growth hormone, artificial growth hormone, synthetic bovine growth hormone, synthetic growth hormone, and their plurals.

2. Both the Claim and the Disclaimer set forth in the preceding subparagraph must meet the following criteria:

⁶ In accordance with the FDA’s February 10, 1994 “Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin,” PDA has evaluated potential and actual labeling statements about rBST in the context of the complete label. PDA has recognized the FDA’s directive that certain labeling statements about the use of rBST may be misleading unless they are accompanied by additional information. Based on the FDA’s intention to rely primarily on the enforcement activities of the interested states to ensure that rBST labeling claims are truthful and not misleading, the number of differing standards that might exist in all fifty (50) states, and recognizing PDA’s relevant authority to regulate such claims is substantially similar in language to the federal authority, PDA acknowledges that uniformity and predictability is brought to the field by close adherence to the FDA’s suggested formulation of labeling statements. Therefore, PDA is reiterating that a clear truthful statement solely about milk production /farming practices, and which does not imply a compositional difference in the milk, is required. However, as stated by the FDA, such an unqualified but admittedly truthful statement can still be misleading and “imply that milk from untreated cows is safer or of higher quality than milk from treated cows,” without more accompanying information. Accordingly, PDA adopts as permissible the FDA’s qualifying statement in the exact form articulated more than a decade ago, which may include the preface “The FDA says....”

- a. The Claim and Disclaimer must be in reasonably legible type, both in terms of style and size,⁷ based upon the entirety and size of the particular label and container under review. In no case may the Disclaimer be less than one-half the size of the Claim.
 - b. The Disclaimer must be visible while reading the Claim and must appear on the same panel of the container as the Claim, except as permitted by special application to the Department.
 - c. Such a special application shall be based upon representations that it is not commercially practical to place the Disclaimer on the same panel as the Claim and requesting that it be located elsewhere provided that a written notation or direction, but not solely an asterisk, such as “See back panel for details,” appears immediately above, below or beside, and contiguous to, the Claim.
 - d. In the case of round containers with one continuous label which encompasses the entire circumference of the container, the same panel requirement may be met so long as the Disclaimer appears in close proximity to the Claim and visible while reading the Claim, or directly under, next to, or above the Nutrition information panel.
3. USDA organic certification shall negate the requirement that the Disclaimer be included.
 4. The Claim cannot be used unless all dairy product ingredients can also be truthfully represented as fitting this description.
 5. The following substantiation must be made available to the Department as part of the label approval process and thereafter upon request for Departmental verification of compliance:
 - a. The permit holder maintains their own procedures to verify the production methods claimed on their label(s) and that all dairy product ingredients truthfully fit this description.
 - b. Any milk or dairy product fitting this description must not be co-mingled with other milk and dairy product from farm to packaged product.
 - c. A paper audit trail that can readily document items a. and b.
 - d. USDA organic certification shall satisfy all substantiation required hereby.

⁷As to the issue of font size, if the font size for capital letters has a cap height of at least 1/16 of an inch, then capital letters, small capital letters (a/k/a small caps) or the combination of capital and lower case letters in the same font that are subject to review under these standards will be given a presumption of legibility. The cap height for the capital letters for the font family used shall be used for ascertaining compliance with the proportionality requirements in provisions 7(A) iii and 7(B)i.2.a. Proportionality shall be measured by the difference between the cap height of the capital letters of the largest font used in a Claim, if font sizes differ within the entirety of the Claim, and the cap height of the capital letters of the smallest font size used in the remainder of the Claim or in the Disclaimer, whichever is the relevant inquiry. For shrink wrapped labels, a variance of approximately 6% associated with the shrink wrap process will be considered reasonable and will not alter the presumption of legibility.

8. Variances. The foregoing is notice of the policy PDA shall apply in exercising its administrative enforcement powers under the Food Act and the Milk Sanitation Law. Reasonable variations from the process and standards described in this policy may be allowed, where the labeling entity demonstrates to PDA that the circumstances warrant a particular accommodation, including, but not limited to, a product label for a product produced at a plant in another State of the United States where that plant's home State already played a role in the development and/or approval of the labeling for which approval is sought under this policy.