



Pennsylvania Department of
AGRICULTURE
Bureau of Food Safety and Laboratory Services

Date: October 22, 2007

Subject: Standards and Procedure for the Approval of Proposed Labeling of Fluid Milk, Milk Products and Manufactured Dairy Products

To: All Fluid Milk, Milk Products and Manufactured Dairy Products 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, milk products and manufactured dairy products 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 milk, milk products and manufactured dairy products.

Regardless of whether approval was previously sought or received for any particular label in the past, the Department is now instituting new internal procedures and policies as outlined in this communication for the approval of milk, milk product and manufactured dairy product labels. Commencing on January 1, 2008, all such labels submitted will be approved in the fashion and according to the guidelines set forth herein.

II. **Standards and Procedure for the Approval of Proposed Labeling - Fluid Milk, Milk Products and Manufactured Dairy Products**

- 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

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).



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- The regulations promulgated under authority of the Milk Sanitation Law prohibit misleading words or endorsements on milk, milk product and manufactured dairy product 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.
- The regulations promulgated under authority of the Milk Sanitation Law require that the labeling for all containers and closures for milk, milk products and manufactured dairy products 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, milk product or manufactured dairy product label is “misleading,” and therefore a “misbranded” food that may not be lawfully sold.

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

Labeling in use as of October 22, 2007, (1) for which approval has not been granted or sought through the application process set forth herein by January 1, 2008; or (2) which has been disapproved by PDA, shall be discontinued as of January 1, 2008.

2. Application required. A permit holder seeking PDA’s approval of milk, milk product or manufactured dairy product 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.

⁴ 7 Pa. Code § 59.21(g).

⁵ 7 Pa. Code § 59.21(d).



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- 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. If the text, type size or wording is to be changed, the label must be submitted to PDA for approval.
- 7. Prohibited label representations.** PDA shall consider it the burden of an applicant to demonstrate the accuracy and verifiability of any proposed label claim or information. PDA shall, in the exercise of its administrative discretion, consider the following to be inaccurate and/or misleading, and for milk, milk products and manufactured dairy products bearing such label representation to be prohibited “misbranded” food under the Food Act:
- (A) A compositional claim which has not been confirmed through laboratory analysis, performed at the applicant’s expense.
- (B) A compositional or production-related claim that is supported solely by sworn statements, affidavits or testimonials.
- (C) Where a specific compound or substance is naturally present in the product, a statement that the compound or substance is not present, or that the compound or substance has not been added, unless supported by laboratory analysis or other scientific testing performed at the applicant’s expense.
- (D) Where a specific compound or substance is prohibited from being present in the product by statute or regulation, a statement that the compound or substance is not present or that the compound or substance has not been added.
- 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.