Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin

[Federal Register: February 10, 1994]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. 94D-0025]

Interim Guidance on the Voluntary Labeling of Milk and Milk Products From Cows That Have Not Been Treated With Recombinant Bovine Somatotropin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing interim guidance on the labeling of milk and milk products from cows that have not been treated with recombinant bovine somatotropin. Several States and industry and consumer representatives have requested guidance from FDA on this issue. This interim guidance is intended to respond to these requests.

DATES: Written comments by March 14, 1994.

ADDRESSES: Submit written comments on the interim guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington DC 20204, 202-205-4681.

SUPPLEMENTARY INFORMATION: On November 5, 1993, FDA approved a new animal drug application providing for the subcutaneous use of sterile sometribove zinc suspension (recombinant bovine somatotropin (rbST) or a recombinant bovine growth hormone (rbGH)) in lactating dairy cows to increase the production of marketable milk (58 FR 59946, November 12, 1993). FDA approved the product because the agency had determined after a thorough review that rbST is safe and effective for dairy cows, that

milk from rbST-treated cows is safe for human consumption, and that production and use of the product do not have a significant impact on the environment. In addition, the agency found that there was no significant difference between milk from treated and untreated cows and, therefore, concluded that under the Federal Food, Drug, and Cosmetic Act (the act), the agency did not have the authority in this situation to require special labeling for milk from rbST-treated cows. FDA stated, however, that food companies that do not use milk from cows

supplemented with rbST may voluntarily inform consumers of this fact in their product labels or labeling, provided that any statements made are truthful and not misleading. Several States and industry and consumer representatives have asked FDA to provide guidance on the labeling of milk and milk products from cows that have not been treated with rbST.

FDA agrees that, with the expiration of the congressional moratorium on the commercial sale of rbST on February 3, 1994, the issuance of guidance would help prevent false or misleading claims regarding rbST. FDA views this document primarily as guidance to the States as they consider the proper regulation of rbST labeling claims. Given the traditional role of the States in overseeing milk production, the agency intends to rely primarily on the enforcement activities of the interested States to ensure that rbST labeling claims are truthful and not misleading. The agency is available to provide assistance to the States.

The guidance presented here reflects FDA's interpretation of the act and may be relevant to States' interpretation of their own similar statutes. This document does not bind FDA or any State, and it does not create or confer any rights, privileges, benefits, or immunities for or on any persons. Furthermore, this document reflects FDA's current views on this matter. FDA may reconsider its position at a later date in light of any comments it receives on this guidance document.

Interested persons may, on or before March 14, 1994, submit to the Dockets Management Branch (address above) written comments on the interim guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

The text of the interim guidance follows:

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Appropriate Labeling Statements

At the Federal level, statements about rbST in the labeling of food shipped in interstate commerce would be reviewed under sections 403(a) and 201(n) of the act. Under section 403(a) of the act, a food is misbranded if statements on its label or in its labeling are false or misleading in any particular. Under section 201(n), both the presence and the absence of information are relevant to whether labeling is misleading. That is, labeling may be misleading if it fails to disclose facts that are material in light of representations made about a product or facts that are material with respect to the consequences that may result from use of the product. Thus, certain labeling statements about the use of rbST may be misleading unless they are accompanied by additional information. This guidance is based on the use of the false or misleading standard in the Federal law, which is incorporated in many States' food and drug laws. States may also have additional authorities that are relevant in regulating such claims.

Because of the presence of natural bST in milk, no milk is ``bST-free,'' and a ``bST-free'' labeling statement would be false. Also, FDA is concerned that the term ``rbST free'' may imply a compositional difference between milk from treated and untreated cows rather than a difference in the way the milk is produced. Instead, the concept would better be formulated as ``from cows not treated with rbST'' or in other similar ways. However, even such a statement, which asserts that rbST has not been used in the production of the subject milk, has the potential to be misunderstood by consumers. Without proper context, such statements could be misleading. Such unqualified statements may imply that milk from untreated cows is safer or of higher quality than milk from treated cows. Such an implication would be false and misleading.

FDA believes such misleading implications could best be avoided by the use of accompanying information that puts the statement in a proper context. Proper context could be achieved in a number of different ways. For example, accompanying the statement ``from cows not treated with rbST'' with the statement that ``No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows'' would put the claim in proper context. Proper context could also be achieved by conveying the firm's reasons (other than safety or quality) for choosing not to use milk from cows treated with rbST, as long as the label is truthful and nonmisleading.

States should evaluate any labeling statement about rbST in the context of the complete label and all labeling for the product, as well as of any advertising for the product. Available data on consumers' perceptions of the label statements could also be used to determine whether a statement is misleading.

Substantiation of Labeling Claims

There is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from cows that do not. Therefore, to ensure that claims that milk comes from untreated cows are valid, States could require that firms that use such claims establish a plan and maintain records to substantiate the claims, and make those records available for inspection by regulatory officials. The producer of a product labeled with rbST claims should be able to demonstrate that all milk-derived ingredients in the product are from cows not treated with rbST. Failure to maintain records would make it difficult for a firm to defend itself in the face of circumstantial evidence that it is using rbST or selling milk from treated cows. In some situations (e.g., dairy cooperatives that only process milk from untreated cows), States may decide that affidavits from individual farmers and processors are adequate to document that

milk or milk products received by the firm were from untreated cows.

States should consider requiring that firms that use statements indicating that their product is ``certified'' as not from cows treated with rbST be participants in a third party certification program to verify that the cows have not been injected with rbST. States could seek to ensure that certification programs contain the following elements: Participating dairy herds should consist of animals that have not been supplemented with rbST. The program should be able to track each cow in the herd over time. Milk from non-rbST herds should be kept separate from other milk by a physical segregation, verifiable by a valid paper trail, throughout the transportation and processing steps until the finished milk or dairy product is in final packaged form in a labeled container. The physical handling and recordkeeping provisions of such a program would be necessary not because of any safety concerns about milk

from treated cows but to ensure that the labeling of the milk is not false or misleading.

Dated: February 17, 1994,
Michael R. Taylor,
Deputy Commissioner for Policy.
[FR Doc. 94-3214 Filed 2-8-94; 9:27 am]
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