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March 31, 2003

Chief, Standardization Branch  
Livestock and Seed Program  
AMS, USDA, Room 2603-S, Stop 0254  
1400 Independence Avenue, SW  
Washington, DC 20250-0254

**Re: Docket No. LS-02-02; United States Standards for Livestock and Meat Marketing Claims**

The ANIMAL HEALTH INSTITUTE (“AHI”) submits these comments to Docket Number LS-02-02: United States Standards for Livestock and Meat Marketing Claims. AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

USDA is proposing to establish minimum requirements for common production/marketing claims that may be used in voluntary USDA Certified or USDA Verified programs for the livestock and meat industries. AHI appreciates USDA’s efforts to bring uniformity to the standards for production/marketing claims on meat products marketed in the USA but believes this proposal could have considerable negative impact on our members. Our comments will be limited to a general comment about misbranding of meat products by labeling that may be false or misleading and to comments concerning two specific types of claims relating to live animal production: (1) Antibiotic Claims and (2) Hormone Claims.

## **I. General Comment**

We want to emphasize our belief in commercial free speech and in consumers’ rights to be informed about the products they purchase. The overriding public policy issue is how to allow factual claims that facilitate the ability of consumers to make informed choices, without allowing the use of claims that are false or mislead the public.

The Federal Meat Inspection Act, the Poultry Products Inspection Act and the Federal Food, Drug, and Cosmetic Act all state that meat, poultry or food is misbranded if “its labeling is false or misleading in any particular.” See 21 USC § 601(n)(1); 21 USC § 453(h)(1); and 21 USC § 343(a). Because these statutes use identical wording, it is appropriate for USDA to look to FDA interpretation and practices in this area under similar circumstances. Indeed, federal

courts interpreting the Federal Meat Inspection Act have looked to cases interpreting identical language in the Federal Food Drug and Cosmetic Act. *See Supreme Beef v. USDA*, 113 F.Supp. 2d 1048, 1052 (N.D. Tex. 2000); *Supreme Beef v. USDA*, 275 F.3d 432, 441 - 442 (5<sup>th</sup> Cir. Tex. 2001). Additionally, federal courts interpreting the Federal Food Drug and Cosmetic Act have looked to identical language in the Federal Meat Inspection Act. *See Nutritional Health Alliance v. FDA*, 318 F.3d 92 (2<sup>nd</sup> Cir. NY 2003).

In addressing a similar type of labeling claim issue, the Food and Drug Administration has developed an interim guidance for the voluntary labeling of milk and milk products from cows not treated with recombinant somatotropin (rbST), 59 Fed. Reg. 6279 (February 10, 1994), which was reaffirmed as FDA policy in December 2002.<sup>1</sup> FDA recognizes that statements that rbST was not used in milk production may lead consumers to conclude that milk from untreated cows is safer or of higher quality than milk from treated cows and that such an implication would be misleading. As a consequence, a producer that labels milk as “from cows not treated with rbST” must also put this statement into context by including information to indicate there is no significant difference between milk from cows treated with rbST and milk from those not treated with rbST. AHI believes that these principles must be incorporated into the production/marketing claims proposed by AMS in order to prevent such claims from being false and misleading.

Analogous to the situation with rbST, label statements that meat was produced without the use of antibiotics, produced without the use of subtherapeutic antibiotics, or produced without the use of supplemental hormones, etc, alone are misleading. They inappropriately lead the consumer to conclude that meat produced from animals where these products are not used is somehow safer or of higher quality than meat produced from animals where they are used. Such label statements must also contain information to put these statements into context. Such accompanying information could be a statement to the effect that “there is no significant difference in safety of meat produced from antibiotic / hormone-treated and non-antibiotic / hormone-treated animals.” Such accompanying information must be as conspicuous as the claim.

AHI recommends that AMS develop and implement a program for Livestock and Meat Marketing Claims that requires the use of accompanying contextual information in order to prevent the claims from being misleading. In addition, AHI recommends that USDA/AMS focus on those issues where the action being proposed as a standard has some meaning to the consumer of the product and avoids creating confusion or issues centered around superiority of any particular production practice over another. The focus should be safe and wholesome food.

The administration of the proposed USDA Certified or USDA Verified programs will require considerable resources. USDA/AMS should consider a fee schedule that will pay for the objective and legally demonstrable means of verifying the production/marketing claims. Fees should be charged to producers who wish to obtain these claims as a means of recovering the costs of the programs.

## **II. Specific Comments**

### **A. Antibiotic Claims**

#### 1. “No Antibiotics Used” – “Raised without antibiotics”

This type of claim implies that no antibiotic was used in the production of the animal from which the meat was derived. In order to be truthful and not misleading, the only meat products that should be permitted to carry such label statements are those derived from animals that have never been given an antibiotic for any purpose in any form. This would include antibiotics administered for disease control, disease prevention, disease treatment, feed efficiency, or any other purpose.

Furthermore, the term “antibiotic” should be defined. Technically, an antibiotic is a substance that is produced by a microorganism and at low concentrations inhibits or kills other microorganisms.<sup>2</sup> The Food, Drug, and Cosmetic Act also defines an antibiotic drug for human use similarly under Section 201, (jj). The word “antimicrobial” has a broader definition than antibiotic and includes any substance of natural, semisynthetic or synthetic origin that kills or inhibits the growth of a microorganism but causes little or no damage to the host “Antimicrobial” is often used synonymously with “antibiotic.” If AMS intends to use a broader meaning of “antibiotic,” which is probably the case, this should be made clear. Moreover, as indicated above, a prominent label disclaimer that meat produced without antibiotics is not of better quality and no safer than meat produced with the use of antibiotics is the only manner in which such label statements can be made truthful and non-misleading.

#### 2. “No subtherapeutic antibiotics added” – “Not fed antibiotics”

This aspect of the proposed scheme should be deleted. The phrase “No subtherapeutic antibiotics added” is misleading. During the processing of meat products, no one adds “subtherapeutic” antibiotics to the meat. However, such a phrase implies that this is a practice.

Furthermore, the FDA’s Center for Veterinary Medicine, in their current guidance document #152, released in October 2002, for evaluating the safety of antimicrobial drugs, does not use this term in describing approved antibiotic or antimicrobial feed additives. Nor is there is a scientific definition of “subtherapeutic.” Defining dosages of antibiotics/antimicrobials is relative to specific bacteria and the minimal inhibitory concentrations needed to suppress or kill them. What may be too low to be therapeutically effective against one species or genus of bacteria may be very effective for other types of bacteria. We recommend that AMS not allow such claims.

The phrase “Not fed antibiotics” is also misleading. It implies that no antibiotics have ever been administered to the animal. The consumer will be unlikely to understand the nuances stated in the proposed scheme and the nuances of production practices.

The use of the terms “No subtherapeutic antibiotics added” or “Not fed antibiotics” when the approved FDA withdrawal period is observed is inherently misleading as it implies that the product is safer than a product not labeled and derived under identical production practices. Furthermore, the consumer may be misled in believing no antibiotic or other animal drugs were used, when in fact that may not be true.

3. “No detectable antibiotic residue (analyzed by ‘method x’)”

The use of the term “No detectable antibiotic residue (analyzed by ‘method x’)” is inherently misleading. The proposed AMS label scheme implies that meat products derived from animals withdrawn for 30 days beyond the minimum FDA withdrawal requirements are of better quality or safer than products derived by observing the FDA requirements. The process for establishing the safety of animal drug residues is based on a highly scientific and conservative process with multiple safety factors applied. This labeling proposal undermines the stringent requirements used for determining the safety of residues from antibiotics and the appropriate withdrawal times. Some antibiotics, e.g., penicillins, have tolerances that are at or below the detectable levels of practical analytical methods at the FDA approved withdrawal times. Also, virtually all antibiotics would be well below any detectable levels at 30 days beyond the FDA approved withdrawal times. We are clearly opposed to such claims, but if allowed by USDA, a prominent label disclaimer that (1) the meat may have been produced from animals administered antibiotics, (2) that a withdrawal period beyond that set by FDA has no scientific basis and does not make the meat safer or of better quality, and (3) that meat produced without antibiotics is not safer or of better quality than meat produced with the use of antibiotics is the only manner in which such label statements can be made truthful and non-misleading.

**B. Hormone Claims**

1. “No supplemental hormones used” – “Raised without supplemental hormones”

This type of claim implies that no hormone was used in the production of the animal from which the meat was derived. In order to be truthful and not misleading, the only meat products that should be permitted to carry these statements are those derived from animals that have never been administered a hormone for production purposes such as weight gain, feed conversion, feed efficiency, or estrus suppression, etc. Moreover, a prominent label disclaimer that meat produced without the use of supplemental hormones is not of better quality and no safer than meat produced with the use of supplemental hormones is the only manner in which such label statements can be made truthful and non-misleading.

The use of the terms “hormone,” “growth promotant,” “growth stimulant,” and “implant” interchangeably is false and misleading. For example, antibiotics are approved to increase weight gain and improve feed efficiency and are not considered hormones. Melengesterol acetate is a hormone that is not administered as an implant; it is only added to the feed. These terms are not interchangeable and should not be used as if they were. For purposes of this proposed meat labeling and marketing scheme, a better approach would be to delete the use of

phrases like “No supplemental hormones used” and “Raised without supplemental hormones” and use “No anabolic hormones used” or “Produced without the use of anabolic hormones.”

2. “No hormones administered during finishing”

The phrase “No hormones administered during finishing” is misleading. Consumers will likely believe no hormones were used in producing the meat, which may not be true. Moreover, a prominent label disclaimer that the meat may have been produced from animals administered supplemental hormones [anabolic hormones], and, that meat produced without the use of supplemental hormones [anabolic hormones] is not safer or of better quality than meat produced with the use of supplemental hormones [anabolic hormones] is the only manner in which such label statements can be made truthful and non-misleading.

3. No use of marketing phrases where there are no approved products

The terms “No supplemental hormones” and “No hormones administered during finishing” should not be allowed in those species that do not have a product approved in that species. For example, it would be false and misleading to allow such a term to be used on a meat product derived from swine or poultry because it would imply that they might be used in other similar meat or poultry products, where such would not be the case.

4. “No hormones”

USDA/AMS should also make a clear statement that the use of terms such as “no hormones” or “produced without hormones” for the marketing of meat is false and misleading. Such a statement, seen at some meat counters, implies there are no hormones in the meat or no hormones in the cow that produced the meat. All meat contains naturally occurring hormones. There is no such thing as meat that does not contain hormones. USDA/AMS implicitly recognizes this fact by only proposing the use of terms referencing supplemental hormones.

### **III. Enforcement to Stop and Prevent False and Misleading Meat Labeling**

The AMS program states it will be voluntary and really only aims to provide “credibility” to the use of the claims by allowing use of the phrase “USDA verified.” Such a program will only address a portion of the issue surrounding the types of labeling and marketing statements referenced in the docket. Meat is currently being marketed using false and misleading claims as in the hormone example above. USDA should stop the use of such false and misleading marketing practices that are in violation of the Federal Meat Inspection Act. By halting false and misleading meat labeling, USDA would provide even greater credibility to the proposed labeling scheme.

If you have any questions or need further information, do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard A. Carnevale". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Richard A. Carnevale

<sup>1</sup>Letter from Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, to Michael D. Dykes, Vice President, Monsanto Company (December 13, 2002)(Copy attached).

<sup>2</sup>Prescott, JF, 2000. Antimicrobial drug action and interaction. In: JF Prescott, JD Baggot, & RD Walker, eds. Antimicrobial Therapy in Veterinary Medicine, 3<sup>rd</sup> ed. Amers, IA: Iowa State University Press. p. 3.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

December 13, 2002

Michael D. Dykes, D.V.M.  
Vice President  
Government Affairs  
Monsanto Company  
600 13<sup>th</sup> Street, NW  
Suite 660  
Washington, DC 20005

Dear Dr. Dykes:

You have requested our view on the voluntary labeling of milk and milk products from cows not treated with recombinant bovine somatotropin (rbST). Any labeling about the use of milk from cows not treated with rbST must be truthful and not misleading under the requirements of the Federal Food, Drug, and Cosmetic Act (the Act).

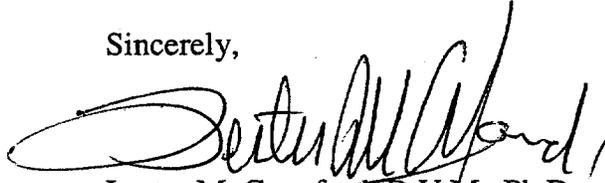
Recombinant bovine somatotropin was approved by the Food and Drug Administration (FDA) on November 5, 1993, as a new drug for use in lactating dairy cows to increase the production of marketable milk (58 FR 59946, November 12, 1993). FDA approved the drug because the agency had determined after a thorough 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 drug do not have a significant impact on the environment. In addition, the agency found there was no significant difference between milk from treated and untreated cows, and, therefore, concluded that under the Act, the agency did not have the authority to require special labeling for milk from rbST-treated cows. However, FDA stated that food companies that do not use milk from cows treated with rbST may voluntarily inform consumers of this fact in their product labels or labeling, provided statements are truthful and not misleading.

Statements that lead consumers to conclude that milk from untreated cows is safer or of higher quality than milk from treated cows would be false or misleading. One way to avoid this outcome is to describe the product as "from cows not treated with rbST." Claims should appear in the proper context with accompanying information, such as "no significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows." Proper context is also 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 claim is truthful and not misleading. Such accompanying information should be placed on the label with such conspicuousness (compared with other words, statements, or designs in the label) and in such terms as to render it likely to be

Page 2 – Mr. Michael D. Dykes, DVM

read and understood by the ordinary individual under usual conditions of purchase and use. Claims that milk and milk products are from cows not treated with rbST should also be substantiated.

Sincerely,

A handwritten signature in black ink, appearing to read "Lester M. Crawford". The signature is fluid and cursive, with a large loop at the beginning and a long, sweeping underline that extends to the left and then curves back under the name.

Lester M. Crawford, D.V.M., Ph.D.  
Deputy Commissioner