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August 10, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket No. 2004N-0257, Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle

Dear Sir or Madam:

The American Dairy Products Institute (ADPI) appreciates the opportunity to submit these comments to the FDA regarding the proposed rule on "Recordkeeping Requirements for Human Food and Cosmetics Manufactured From, Processed With, or Otherwise Containing, Material From Cattle." ADPI, headquartered in Chicago, is the trade association of the nation's leading manufacturers and processors of processed dairy ingredients, including whey and whey protein concentrates, nonfat dry milk, evaporated milk, and lactose. Because all of these ingredients are derived from milk, ADPI has a strong interest in any regulation that broadly impacts the production of cattle-derived food products and ingredients. We respectfully submit the following comments.

BACKGROUND

On July 14, 2004, FDA published a proposed rule on recordkeeping requirements to ensure compliance with the companion interim final rule. 69 Fed. Reg. 42275. The interim final rule on "Use of Materials Derived From Cattle in Human Foods and Cosmetics" prohibits the use of certain cattle materials in human food (including dietary supplements) and cosmetics. 69 Fed. Reg. 42255. The interim final rule states that human food may not be manufactured from, processed with, or otherwise contain "prohibited cattle materials." Prohibited cattle materials include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and/or mechanically separated (MS)(Beef). ADPI is not commenting on the interim final rule at this time.

ADPI'S CONCERN

Our review of the proposed rule reveals a potential, albeit probably unintended, impact on the processed dairy industry. The application of the recordkeeping requirements is broadly worded. The proposed rule states that all manufacturers/processors of human food that contain "material from cattle" must maintain records verifying that these cattle materials comply with the interim final rule. The term "material from cattle" is not defined in the proposed rule or in the

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interim final rule. A strict reading of the proposed rule suggests that every product that contains cattle-derived material is covered by these recordkeeping requirements without exception.

We do not believe that FDA actually intended to draft the rule without an exception for dairy products, because the types of records that must be kept are explained in the preamble as certification from the slaughter establishment, which would not be relevant to materials used by dairy manufacturers/processors. Examples used in the proposed rule of human food containing cattle material include soup containing beef broth and dietary supplements containing cattle brain powder. There is no mention of milk or other dairy products in the proposed rule or in the interim final rule. Also, part of the justification for the proposed rule is that "[once material is removed from cattle, we may not be able to obtain the information necessary to determine whether it is prohibited cattle material.]" We do not believe there is any realistic possibility of confusion of dairy products with prohibited cattle materials in foods or cosmetics. Furthermore, dairy products are not known to present any risk of BSE to consumers. In fact, FDA's document titled "Commonly Asked Questions About BSE in Products Regulated by FDA's Center for Food Safety and Applied Nutrition (CFSAN)"[1] reports the following question and answer:

> Is cow's milk a source of BSE?
>
> Scientific research indicates that BSE is not transmitted in cow's milk, even if the milk comes from a cow with BSE. Milk and milk-derived products, even in countries with a high incidence of BSE are, therefore, considered safe.

ADPI'S RECOMMENDATION

In light of the discussion above, ADPI respectfully submits that a definition of "material from cattle" is needed to clarify which types of products are covered by the recordkeeping requirements and to ensure that manufacturers and processors of foods and cosmetics containing dairy products as the only cattle-derived material are exempt from this requirement. Alternatively, proposed 21 C.F.R. § 189.5(c)(1) could be amended as follows:

> (c)(1) Records. Manufacturers and processors of human food that is manufactured from, processed with, or otherwise contains, material from cattle <u>(excluding milk and milk-derived products)</u> must establish and maintain records sufficient to demonstrate that the food is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

The corresponding proposed rule affecting cosmetics, 21 C.F.R. § 700.27(c)(1), would then be amended as follows:

> (c)(1) Records. Manufacturers and processors of a cosmetic that is manufactured from, processed with, or otherwise contains, material from cattle <u>(excluding milk and milk-derived products)</u> must establish and maintain records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.

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[1] Available at http://vm.cfsan.fda.gov/~comm/bsefaq.html (last visited August 6, 2004).

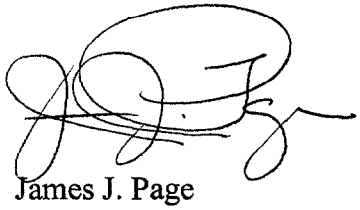
RELEVANT PRECEDENT

Similar confusion occurred when USDA-APHIS issued the interim final rule on the prohibited importation of animal products from BSE-affected countries. Title 9 of the Code of Federal Regulations, section 94.18, outlines the restrictions on the importation of meat and edible products from ruminants due to BSE. The initial interim final rule stated that the importation of "edible products other than meat from ruminants" is prohibited. It was not clear whether this language referred to milk and milk-derived products for human consumption as, technically, milk and milk products are edible products other than meat and are from ruminants. Comments to the interim final rule flagged this issue and claimed that including milk and milk-derived products would prohibit the importation into the United States of a large volume of milk and dairy products. *See* 56 Fed Reg. 63865 (Dec. 6, 1991). USDA-APHIS responded that it had not intended to exclude milk and milk products from importation. As is the case here, the context of the regulations implied that the term referred to products that result from the slaughter of ruminants, not from milking. However, in order to eliminate any potential confusion, USDA-APHIS changed the language in section 94.18 to read "edible products other than meat (excluding gelatin, milk, and milk products)."

CONCLUSION

In sum, ADPI believes that FDA inadvertently worded the proposed rule in an overly broad manner such that dairy products were unintentionally included in a strict reading of the rule. If, for any reason, FDA actually did intend for manufacturers and processors of foods and cosmetics containing dairy products to fall within the scope of the proposed rule, ADPI respectfully requests that FDA reopen the comment period to allow the dairy industry to more fully comment on the proposed rule before it is finalized. Again, ADPI appreciates the opportunity to comment on the proposed rule. Please feel free to contact us if FDA has any questions with respect to our comments.

Respectfully submitted,



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