



**Consider the Use of Activated Charcoal, Mineral Oil, Bismuth Subsalicylate, Kaolin  
Pectin, and Other Livestock Medications  
Used in Operations Regulated by 7 CFR 205 (USDA's National Organic Program)  
as Minor Uses under the Minor Use and Minor Species Animal Health Act**

*Submitted by:  
Tom Hutcheson  
Associate Policy Director  
January 10, 2005*

Thank you very much for the opportunity to comment on the Minor Use and Minor Species Animal Health Act (MUMS). The Organic Trade Association (OTA) requests that the use of livestock medications in organic livestock production be designated as a "minor use" due to the legally distinct and *de facto* limited nature of organic livestock production. The use of materials in organic production would therefore be minor, and the allowance of such materials would be regulated by 7 CFR 205, including review by the National Organic Standards Board (see below).

OTA is the sole trade association representing the entire organic industry in the U.S. and Canada, with approximately 1500 members, including growers, livestock producers, manufacturers, distributors, retailers, and others involved in the organic industry.

7 CFR 205, covering organic production and processing, includes strict rules regarding synthetic materials used in organic production. For example, while vaccinations using synthetic medications are allowed for use in livestock production, animals that have been treated with antibiotics must be removed from organic production. Synthetic materials proposed for use in organic production must be petitioned and are rigorously reviewed according to stringent criteria (required both by the enabling legislation and the Final Rule) by the National Organic Standards Board (NOSB), which is appointed by the Secretary of Agriculture. This is true of these ten materials, so OTA is not proposing that materials be allowed for use without any review.

In the past, some applications of livestock medications have been considered off-label uses, and therefore some materials have been recommended for allowance in organic livestock production by NOSB have not been allowed as medical treatments by FDA.

On June 23, 2003, FDA notified USDA's National Organic Program (NOP) that ten synthetic substances would not be approved for use under current rules. OTA believes that at least these materials, which have been reviewed by NOSB, qualify to be allowed under MUMS. The materials are:

**Headquarters:** 60 Wells Street, P.O. Box 547, Greenfield, MA 01302 USA • (413) 774-7511  
Fax: (413) 774-6432 • e-mail: [info@ota.com](mailto:info@ota.com) • web site: [www.ota.com](http://www.ota.com)  
**Legislative Office:** 600 Cameron Street, Alexandria, VA 22304 USA • (202) 338-2900  
Printed on Recycled Paper



- activated charcoal;
- bismuth subsalicylate;
- butorphanol;
- calcium borogluconate;
- calcium propionate;
- kaolin pectate;
- magnesium hydroxide;
- magnesium oxide;
- mineral oil; and
- potassium sorbate.

Accordingly, OTA requests not only that organic livestock production be considered a minor use, but that these ten materials specifically be allowed for use under MUMS.

Furthermore, OTA urges FDA to work with USDA's NOP and NOSB to resolve any similar issues, such as creating appropriate regulatory categories for the codification of synthetic materials used under 7 CFR 205 but not specifically listed with FDA, in order to maintain a level playing field for organic livestock producers relative to conventional livestock producers.

Thank you very much for your consideration.

**Headquarters:** 60 Wells Street, P.O. Box 547, Greenfield, MA 01302 USA • (413) 774-7511

Fax: (413) 774-6432 • e-mail: [info@ota.com](mailto:info@ota.com) • web site: [www.ota.com](http://www.ota.com)

**Legislative Office:** 600 Cameron Street, Alexandria, VA 22304 USA • (202) 338-2900

Printed on Recycled Paper

