Northeast Organic Dairy Producers Alliance

NODPA

Arthur Neal
Director of Program Administration
USDA-AMS-TMP-NOP
Room 4008-South Building
1400 Independence Avenue, SW
Ag Stop 0268
Washington, DC 20250

Comments on: Docket TM- 03-04

September 15th 2006

Dear Mr. Neal:

NODPA would like to thank the NOP for moving forward on adding livestock materials to the National List and for taking public comment into consideration. This letter and comments are submitted by the Northeast Organic Dairy Producers Alliance (NODPA) in conjunction with the Midwest Organic Dairy Producers Association (MODPA) and the Western Organic Dairy Producers Alliance (WODPA).

NODPA is the largest organic dairy farmer organization in the country and has a membership of six hundred and sixty organic dairy farmers. NODPA's mission is to "**enable organic dairy family farmers, situated across an extensive area, to have informed discussion about matters critical to the well being of the organic dairy industry as a whole**."

NODPA is not aligned with any one processor or cooperative and is therefore able to represent the views of many different farmers both in the northeast and across the country by working with its sister organizations, MODPA and WODPA.

Materials proposed for addition to the List

The materials being proposed by the NOP for addition to the National List appear to be ones that would seldom have application in organic systems, but there are times when they could be used to help re-achieve health and to limit animal pain and suffering. They appear to be short lived drugs or

30 Keets Rd, Deerfield, MA 01342 Tel: 413-772-0444 Fax: 866-554-9483
email: ednodpa@comcast.net web: www.organicmilk.org or www.nodpa.com

materials that are not likely to be absorbed into an animals system, so seem consistent to be added to the list. Of these materials, the three that we see the most need for would be xylazine for surgical procedures, tolazoline as an antidote for xylazine, and poloxalene for emergency treatment of bloat.

The poloxalene annotation recommended by the NOSB, "for emergency treatment of bloat", needs to be retained to not authorize additional uses for poloxalene that the NOSB did not approve.

Calcium propionate should not be listed as a feed additive. This is a synthetic preservative that the NOSB only intended for use in herbal remedies for health care, not for use in feed. The proposed policy on excipients will permit this use, so it is not necessary to extend this allowance broadly to feed.

In adding these materials to the National List, NODPA believes, however, that it is imperative for the NOP to follow the intent of the NOSB recommendation of establishing extended withdrawal times for these materials, as extra assurance to our product customers. Since the doubling of label withholding times is problematic per the FDA, we are supportive of instead going to specifically established withdrawal times for each material, consistent with the NOSB's recommendations. Such specifically established withdrawal times would follow the precedent set in the existing National List for lidocaine, procaine, etc. We support the following annotations and withdrawal times which are two times the withdrawal times established by the Food Animal Residue Avoidance Databank, (FARAD, www.farad.org) an up-to-date computerized compilation of data sponsored by USDA – CSREES as a guide for livestock producers, veterinarians, and extension personnel. This database includes information from current labels and new animal drug applications, including the official tolerances for drugs and pesticides in tissues, eggs and milk. It also includes data on the fate of chemicals in food animals that is frequently published in the in the Journal of the American Veterinary Medical Association.

- **Atropine** - Federal law restricts this drug to use by or on the lawful order of a licensed veterinarian. Use requires a withhold time of 56 days after administering to livestock intended for slaughter and 12 days after administering to dairy animals.
- **Bismuth subsalicylate** - Federal law restricts this drug to use by or on the lawful order of a licensed veterinarian, in full compliance with the Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.'
- **Butorphanol** - Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations, with required withhold period of 8 days for dairy animals and 42 days for slaughter stock
- **Flunixin** - required withhold period of 6 days for dairy animals and 42 days for slaughter stock
- **Furosemide** - required withhold of period of 4 days for both dairy animals and slaughter stock
- **Magnesium hydroxide** - Federal law restricts this drug to use by or on the lawful order of a licensed veterinarian, in full compliance with the Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations."
- **Poloxolene** - for emergency treatment of bloat

- **Tolazoline** - Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations, for emergency use to counter the effects of xylazine, required withdrawal of 4 days for dairy animals and 8 days for slaughter stock
- **Xylazine** - Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations, for emergency use only, required withdrawal of 4 days for dairy animals and 8 days for slaughter stock

In order to adhere to established procedure and to not abrogate the materials authority vested in the NOSB by OFPA, we believe that the NOSB must be consulted to give their approval to established withdrawal dates on these materials, prior to the NOP moving ahead. But to put these materials on the National List **without** any withdrawal times would be contrary to the will and intent of the NOSB, and would authorize additional uses that the NOSB did not approve.

Materials recommended by the NOSB but not proposed for addition to the List

In actuality, it is the materials not proposed to be added to the list--activated charcoal, calcium boro-gluconate, calcium propionate (for milk fever), kaolin pectin, mineral oil, and propylene glycol--that are of most importance to organic dairy producers as many are key livestock health care materials. We urge the NOP to either add them to the list or to acknowledge that they are already allowable per the existing rule—i.e. that calcium boro-gluconate is allowable by virtue of the fact that it is an electrolyte. We understand the dilemma that the NOP is faced with given that the materials in question are not "FDA approved" drugs, but it seems that the determination by the FDA that thousands of health care materials (of which these are a small number) are legally available over the counter for use in livestock by virtue of their status of "allowed by discretion", should allow the NOP to legally add these materials to the National List.

The June 24, 1994 FDA memo (signed by Alison Martini, Veterinary Medical Officer with the Center for Veterinary Medicine, and approved by William Price, Deputy Director, Division of Animal Feeds) describing substances that are allowed by discretion and / or that are 'low regulatory priority and can be marketed over the counter' supports the allowance for placement of these materials on the National List. These products that are allowed by FDA discretion have long been and are currently widely marketed and extensively used by the conventional livestock industry all across this country. Not only are these NOSB approved livestock materials recognized by this FDA 'discretion' but so are materials already on the National List, such as nutrient vitamins, minerals that are recognized by AAFCO, oral electrolytes, and aspirin. Since these materials already do appear on the National List, it does not seem there would be reason to not also include the additional materials on the National List as well. The materials are all consistent with organic principles and are needed by organic livestock producers as there are no suitable natural alternatives.

Adding these materials to the list with an annotation such as "allowed for use at the discretion of the Food and Drug Administration" should make these acceptable to the FDA. Additionally, products based on non-synthetic active ingredients "of low regulatory priority" should be considered

permitted. For instance, although NOSB voted to consider activated charcoal synthetic, the TAP review indicates that some sources may be non-synthetic. The FDA notes in their 1994 memo that "natural charcoal" is "not considered dangerous to the health of livestock." The 2002 NOSB voted annotation for kaolin pectin states that kaolin-pectin should be allowed "when formulated from either synthetic or natural pectin".

Peroxyacetic Acid

NODPA fully supports the listing of peroxyacetic / peracetic acid with the annotation for use as an equipment/facility sanitizer. Peroxyacetic acid is a more effective sanitizer than chlorine because of its much longer kill life, in addition to it being considerably more environmentally friendly.

Excipients

NODPA is supportive of allowing the use of excipients in health care products but does recognize that there should be some limits on what excipients are allowed—in order to not allow the inclusion of possibly toxic or inappropriate materials for organic production. The proposed candidates for use –either as approved food additives, GRAS substances, or substances included in FDA drug reviews (NADA or NDAs)--provide a reasonable basis for consideration of common additives found in livestock medications. We assume that these excipients are also permitted for use in formulations based on herbal products or other non-synthetic active ingredients consistent with the organic regulations.

We support the addition of a new definition, based on the FDA guidance cited at FR 40629.

> **Excipient:** Any inactive ingredient that is intentionally added to therapeutic or diagnostic products but that are not intended to have therapeutic affects at the intended dosage although they may act to improve product delivery.

Epinephrine / Adrenaline

NODPA supports epinephrine / adrenaline being added to 205.604 with the annotation "Except for emergency treatment of anaphylactic shock, subject to the discretion of the Food and Drug Administration", per the NOSB's recommendation for limited use of this natural material.

Ivermectin annotation

NODPA also asks that the Rule annotation for Ivermectin to be amended to reflect the NOSB recommendation to add "slow release formulations such as the SR (slow release) bolus are prohibited".

Moxidectin

The NOSB recommended the addition of Moxidectin to the National List as a synthetic substance allowed for use in organic livestock production, under a similar annotation as that specified for Ivermectin. The NOSB's rationale for this approval included the fact that Moxidectin is less toxic to soil insects and has less persistence in the environment.

Moxidectin was not petitioned for use as an antibiotic. It is not licensed by FDA for use as an antibiotic[1], and reportedly has no antibacterial or antimicrobial action,[2] although it is structurally classed as a macrolide antibiotic. Accordingly, we recommend the addition of Moxidectin to the National List at 205.603((a)(19) under the reasoning that it is in the same category—but less toxic—than a material already included on the National List. The annotation should be amended to be consistent with 205.238(c)(5) and to indicate it is not used as an antibiotic:

205.603 (13) (ii)Moxidectin: – control of internal parasites only, prohibited for slaughter stock, allowed in breeder stock prior to the last third of gestation. Milk or milk products from a treated animal cannot be labeled as organic for 90 days following treatment.

If Moxidectin is added to the National List, then a more serious look could be taken at removing the more environmentally unfriendly Ivermectin from the List when it comes up again for sunset review.

Pheromones

Finally, the NOSB did recommend adding pheromones to the National List for livestock use in October 2002, with a restriction similar to that currently provided in the crop section at 205.601(f) with allowance for List 3 inerts when used in traps. Pheromones would be useful non-toxic tool for use in livestock facilities to control flies and other pests, and a number of commercial products are in fact available. We request this material be added to the List as follows:

205.603 (f) As insect management:- Pheromones

205.603(e) as synthetic inert ingredients…
(2) EPA –list 3 inerts of unknown toxicity, for use only in passive pheromone dispensers.

NODPA appreciates the NOP taking producer and other public comment into consideration as you work to finalize these regulations based on NOSB recommendations.

Sincerely,

Kathie Arnold

Kathie Arnold, NODPA Board member and Chair of the NODPA Policy Committee

[1] TAP Review conducted for NOSB, Moxidectin, 2003 p.3
[2] Bill Clymer, Fort Dodge Animal Health, public testimony April 20, 2005, NOSB transcript, p 258 et. seq. http://www.ams.usda.gov/nosb/transcripts/April2006/042006NOSBMtg.pdf

Steve Morrison, President, Northeast Organic Dairy Producers Alliance

Steve Pechacek, President, Midwest Organic Dairy Producers Association and Organic Choice

Ward Burroughs, Acting Chair, Western Organic Dairy Producers Alliance