



September 15, 2006

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

Dear Mr. Neal:

OMRI thanks you for the opportunity to comment on the proposed changes to the National Organic Program rule published in *Federal Register* docket TM-03-04 (71 *Federal Register* 40624-40632). We have long anticipated this docket and are grateful that the NOSB's recommendations were proposed. OMRI acknowledges that the subject of animal medications is perhaps the most difficult for the NOP to address and offers its comments in the spirit of working together.

In preparing our comments, we consulted with our Advisory Council (which includes several practicing veterinarians and animal scientists) as well as certifiers with whom we work, and active certified organic dairy and meat producers. In general, OMRI supports the NOP proposals where they closely reflect the NOSB's recommendations and opposes the NOP's proposals where they do not. OMRI is concerned by the differences between the proposal and the NOSB's recommendations; by the lack of information on the consultations with the NOSB, Federal agencies, and all stakeholders; and by the lack of reasons for rejecting the NOSB's recommendations in the context of the criteria established by the Organic Foods Production Act. OMRI has prepared an attached table with our suggested revisions to the National List to meet the NOSB's intent.

Support for Peracetic Acid and Excipients

OMRI supports the listing of peroxyacetic / peracetic acid with the annotation. OMRI also supports, with reservations, the proposal for excipients. The impact of the proposed annotation for excipients is unclear, given the ambiguity noted with the NOSB recommended substances that were not proposed for addition to the National List. In general, OMRI supports having clear guidance on excipients and applauds the efforts by the NOP to provide that. OMRI is concerned that the proposal is at once too broad because it refers to two categories, Generally Regarded as Safe and food additives, that are not related to the approval of drugs, or too narrow because it

leaves out references to treatments that are allowed by FDA discretion. Despite those concerns, OMRI finds the proposal preferable to the ambiguity of not having excipients referred to in the NOP rule. In order to prevent any further confusion, OMRI suggests that the NOP add the following definition for ‘Excipient’ to 7 CFR 205.2:

“Excipient. An ingredient that is intentionally added to a drug for purposes other than the therapeutic or diagnostic effect at the intended dosage.”

OMRI thinks that it is extremely important that the allowance of ‘excipients’ does not create a loophole that permits synthetic ingredients to be used as non-nutritional additives in feed, such as anti-oxidants, preservatives, dust suppressants, and other ingredients historically prohibited for use in organic livestock feed. By clearly defining such substances as limited to those used for health care, they will be used only for therapeutic and diagnostic purposes and not on a routine basis.

Animal Drugs Permitted by FDA Discretion

However, OMRI cannot support any of the other proposals because they do not accept the NOSB’s recommendations and the NOP does not give reasons consistent with the OFPA and organic principles for not accepting the NOSB’s recommendations. While OMRI does not wish to see rulemaking delayed even longer for these substances, OMRI cannot support the rejection of the NOSB’s recommendations based on the reasons given in the docket.

OMRI is particularly concerned with the substances that the NOSB recommended but the NOP did not propose: activated charcoal, calcium borogluconate, calcium propionate (for milk fever), kaolin pectin, mineral oil, pheromones, potassium sorbate, and propylene glycol. The NOP states broadly and repeatedly, but without any apparent basis, that the recommendations could not be accepted based on the consultations with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA). OMRI requests that the full text of the FDA’s and EPA’s consultations be made a matter of public record and used to instruct the NOSB when considering future petitions. The NOSB should be consulted on the NOP proposed revised annotations and accept them in order for those substances to appear as proposed on the National List. NOSB recommendations included annotations that need to be included in the final rule. Proposals that disregard or weaken the recommended annotation threaten to add uses and applications to the National List in defiance of the NOSB’s recommendation.

OMRI asks the NOP to check the transcripts and address the NOSB recommendations for pheromones and potassium sorbate as well. According to our records, the NOSB recommended to add pheromones and List 3 inert ingredients used in passive pheromone dispensers to the National List for livestock production at the October 2002 meeting.

The NOSB also recommended potassium sorbate for use in aloe vera products at the September 2002 meeting. The docket does not mention the NOSB’s recommendations for pheromones and potassium sorbate. Pheromones for insect control are regulated by EPA, not FDA. OMRI is uncertain why the NOP did not propose adding pheromones and their inert ingredients. The proposed amendments actually address potassium sorbate indirectly in the excipients policy, so no action is needed.

The remaining comments on this section address the six items identified as remaining prohibited for use in organic production while they “remain in consultation”: activated charcoal, calcium borogluconate, calcium propionate (for milk fever), kaolin pectin, mineral oil, and propylene glycol. The docket does not explain what “remains in consultation” means. Please refer to 7 CFR 205.600 which cites 7 USC 6517 and 7 USC 6518 regarding the procedure and criteria for amending the National List. In particular, see 7 USC 6517(c)(1)(A) of the OFPA. Our understanding is that the NOP cannot reject NOSB recommendations unless, in consultations with FDA and EPA, the NOP determines that the recommended uses and application of a given substance is:

- 1) harmful to human health or the environment;
- 2) not necessary to the production or handling of the agricultural product because a wholly natural substitute product is available; and
- 3) inconsistent with organic farming and handling.

OMRI requests that in such cases where the NOSB’s recommendations are not accepted, the NOP should explain why they are not accepted, based on the criteria found in the OFPA, with reference to the criteria found in 7 USC 6518(m).

There was nothing in the petition, the TAP review, or any additional information submitted to the NOSB to indicate that the recommended substances were harmful to human health or the environment. The recommended substances are simple remedies that quickly pass through an animal’s system and do not pose any documented problems with residues in milk or meat. They are widely available and have been commonly used by producers as well as veterinarians with no noted serious impacts on the environment.

With reference to 7 USC 6517(c)(1)(A)(ii), OMRI is unaware of any wholly natural substitutes for these substances that are known to work. The NOSB clearly considered them to be consistent with organic farming and handling. Prohibiting these substances means depriving farmers, their animals and veterinarians of key health care treatments. If the USDA is not going to add these substances to the National List, then the statements made in the *Federal Register* notice explaining why the NOSB’s recommendations were not accepted contradict precedent with the current National List, public statements made by FDA officials, and previous actions by the National Organic Program.

It is clear that the Food, Drug, and Cosmetic Act (FDCA) gives FDA the authority to regulate animal drugs. However, FDA officials have acknowledged at NOSB meetings that they do not have authority over organic standards. The NOP rule acknowledges this by making it a violation for any livestock producer to ‘[a]dminister animal drugs in violation of the Federal Food, Drug, and Cosmetic Act.’ [7 CFR 205.238(c)(6)].

The most relevant FDA testimony to this proposal is in the October 22, 2003, NOSB meeting, in particular, this quote from Dr. Steven Vaughn and Dr. Vitolis Vengris of the FDA:

“We can’t tell you what’s organic or not organic and you can’t tell us what can be legally marketed as a drug or what can’t be marketed as a drug.”

<http://www.ams.usda.gov/nosb/transcripts/NOSBMeetingOctober2203WashingtonDC.pdf>
p. 70.

In testimony before the NOSB, FDA officials acknowledged that there are 3,000 medications that are allowed by discretion. If the substances are illegal to use under FDA, then the FDA should enforce the law against the sellers of the illegal drugs as well as non-organic producers. Of those thousands of medications allowed by discretion, the NOSB has recommended six identified as such in the *Federal Register* notice.

The NOP also received from the FDA a memorandum dated June 24, 1994, signed by Alison Martini, Veterinary Medical Officer with the Center for Veterinary Medicine, and approved by William Price, Deputy Director, Division of Animal Feeds. The memo describes substances that are allowed by discretion and/or that are “low regulatory priority and can be marketed over the counter.” The last statement was taken to mean that the FDA has established that these drugs can be legally sold over the counter, depending on the label and oversight by a veterinarian. Health care items considered include both petitioned substances as well as substances that already appear on the National List. The Martini memorandum recognized various substances allowed by FDA discretion that now appear on the National List and are used by certified organic operations, such as nutrient vitamins and minerals that are recognized by AAFCO, as well as oral electrolytes.

In addition to the Martini memorandum, there is a substantial body of evidence that products allowed by discretion or are a low regulatory priority are sold legally over the counter throughout the United States. Conventional farmers routinely use these substances without any penalty or threat of legal action. The FDA allows these medications by discretion for livestock producers all around the country, and therefore they are not in violation of the FDCA.

The inclusion of aspirin at 7 CFR 205.603(a)(2) with the annotation “approved for health care use to reduce inflammation” set a clear precedent that medications that are not explicitly approved by the FDA can be included on the National List. The inclusion of electrolytes at 7 CFR 205.603(a)(6), hydrogen peroxide at 7 CFR 205.603(a)(9), magnesium sulfate at 7 CFR 205.603(a)(11), and copper sulfate at 7 CFR 205.603(b)(1) appear to further bolster the case that drugs approved by FDA discretion or are considered a “low regulatory priority” can be added to the National List provided that they are consistent with OFPA criteria and are recommended by the NOSB.

If the logic that animal medication allowed by FDA discretion should not be permitted for use in organic production were applied to nutrient vitamins and minerals, then those nutrients that are on the AAFCO list and allowed by FDA discretion but are not 21 CFR should not be permitted either. OMRI suggests that as long as the TAP review clearly establishes that an animal drug is allowed by FDA discretion and the FDA has not placed that substance on 21 CFR 530.41 as prohibited for extra-label use, then any drug recommended by the NOSB should be added to the National List along with the recommended annotation.

It is unjust for the NOP to prevent organic producers from using such animal drugs that the NOSB has determined (1) are not harmful to human health and the environment; (2) have no known natural substitutes; and (3) are consistent with organic production based on the criteria found in OFPA. Given that pharmaceutical companies sell and conventional producers use these medications at FDA's discretion without facing prosecution, the prohibiting of these NOSB recommended substances by the NOP unfairly penalizes organic farmers and risks the health of organic animals. Given that the FDA in fact allows these substances to be used on farms across the United States, the NOP should accept the NOSB's recommendations or provide reasons consistent with OFPA why these substances should not be accepted.

OMRI suggests that activated charcoal, calcium borogluconate, calcium propionate, mineral oil, and propylene glycol be added to the National List with the NOSB's recommended annotation and the phrase, 'subject to the discretion of the Food and Drug Administration.'

Ivermectin and Moxidectin

OMRI also objects to the docket not proposing either the revised annotation for ivermectin or adding moxidectin. If ivermectin is acceptable for use in organic production, then moxidectin should also be acceptable. While OMRI recognizes that both substances may be considered macrolide antibiotics, they were recommended to be used only as parasiticides. The annotation could explicitly prohibit any use as an antibiotic.

Some experts consider moxidectin to be more consistent with organic farming practices than ivermectin because it is less persistent and hence less damaging to soil organisms. The NOP should also accept the NOSB's recommendation to prohibit slow-release boluses of ivermectin, based on the environmental impact of such formulations. While slow-release boluses are no longer marketed in the US, ivermectin should nonetheless carry an annotation that reflects such formulations are not consistent with organic production and handling, because such boluses may be available in other countries where animal production is being certified under the USDA organic seal.

Neither ivermectin nor moxidectin would be administered to organic slaughter stock or to breeder stock in their last third of gestation based on 7 CFR 205.238(c)(5) and 7 CFR 205.238(b)(1) respectively. Dairy animals treated with moxidectin would be subject to the 90 withdrawal period specified in 7 CFR 205.238(b)(2) however the annotation reads.

Proposed Annotations Not Accepted

The NOP has proposed annotations that differed from the NOSB's recommendations without first publicly consulting with the NOSB. OMRI requests that the NOP consult with the NOSB before those proposed annotations go into the final rule. In addition, references to Federal Law, and in particular to AMDUCA and 21 CFR 530, as well as to approved labeling, are redundant with the existing requirement that "[t]he producer of an organic livestock operation must not: . . . [a]dminister animal drugs in violation of the Federal Food, Drug, and Cosmetic Act . . ." [7 CFR 205.238(c)(6)].

Further, the NOP did not accept annotations recommended for most of the substances that it proposed to add to the National List. In particular, the NOP has eliminated the extended withdrawal period recommended by the NOSB for flunixin, furosemide, butorphanol, tolazoline, and xylazine, because the NOP claims that the NOSB does not have the authority to do so. The premise is that this would require additional label claims beyond what is permitted by the FDA. However, the NOSB did not require a label change. If ivermectin, lidocaine, and procaine can have extended withdrawals in the rule, then flunixin, furosemide, butorphanol, tolazoline, and xylazine can have extended withdrawals in the NOP rule as well. Not accepting extended withdrawals is equivalent to adding usage to the National List without the NOSB's recommendation.

The National List already includes ivermectin, lidocaine, and procaine for use as livestock medications with extended withdrawals. Given this precedent, the NOP has the authority to establish standards that are stricter for animal drug use than the FDA by the fact that the vast majority of FDA approved drugs are prohibited for use in organic production. Also, all drugs permitted for use in organic farming are subject to stricter standards than those used by non-organic farmers because they are subject to certifiers' review and approval in an Organic System Plan.

The authority that the NOP has over FDA regulated animal drugs is analogous to the restrictions added to the use of EPA regulated pesticides. The NOP does not have the authority over how pesticides are labeled, but the NOP does have authority over how pesticides are applied on organic farms. In addition to the animal drug examples given above, the NOP also sets additional requirements on the use of fixed coppers, soap-based herbicides, and boric acid, among other things. As stated above, FDA officials have indicated that they do not have the authority to regulate organic standards. OMRI urges the NOP to accept the NOSB recommendations for extended withdrawals when applicable, as again these were considerations taken into account based on OFPA criteria. As long as the extended withdrawal is strictly for organic, and is not extended to conventional producers, the NOP has the authority to restrict the use of animal drugs. OMRI suggests that the NOP establish withdrawal periods for organic animals that fulfills the NOSB's intent without reference to the label or requiring any change in the label.

OMRI also supports the NOSB's recommendations to restrict poloxalene, tolazoline, and xylazine for use only as emergency treatments. The FDA publicly indicated its willingness to allow more stringent use of materials as a condition for organic use. Thus, we recommend that the Secretary re-instate the NOSB's recommendations for approval of these materials for emergency use only under the supervision of a licensed veterinarian. The NOSB did not vote to recommend routine use of these substances. By doing so, the Secretary would be allowing uses not recommended by the NOSB.

However, it is OMRI's opinion that the OFPA does not permit the NOP to add synthetic substances to the National List for uses that the NOSB has not recommended. By setting a restriction that is lower than what the NOSB recommended, the NOP is effectively allowing synthetic substances to be used in ways that the NOSB did not intend. If the NOP, for reasons that it considers consistent with organic production, believes that shorter withdrawal times are needed, it should explain to the public why, based on the criteria set forth in OFPA and consult

with the NOSB. Before adopting unspecified, presumably shorter withdrawal times for atropine, flunixin, furosemide, butorphanol, tolazoline, and xylazine, OMRI urges the USDA to poll the NOSB. If the NOSB accepts the NOP's suggested shorter withdrawal periods, then OMRI supports the items being added to the National List.

OMRI suggests that instead of basing the withhold time on the label, that the NOSB's intent can be fulfilled by calculating the withhold time from the USDA sponsored Food Animal Residue Avoidance Database (FARAD) and account for an extra margin of at least double withhold times to safely capture the NOSB's intent. Suggested withdrawal times are summarized in the table below and are also included with suggested annotations in the attached table.

Substance	Milk Withhold	Meat Withhold
Atropine	12 days	56 days
Butorphanol	8 days	42 days
Flunixin	6 days	42 days
Furosemide	4 days	4 days
Tolazoline	4 days	8 days
Xylazine	4 days	8 days

Nonsynthetic Substances Not Prohibited

The NOP did not propose to prohibit the naturally occurring substance epinephrine with an annotation to restrict its use to emergency treatment for anaphylactic shock. The reason given that existing laws cover use and application may have merit, but OMRI suggests that that reason was unclear in the TAP review, and, for that reason, the NOSB recommended adding it to the National List to give greater clarity. OMRI asks that the NOP consult with the NOSB regarding the recommendation for epinephrine, and if the NOSB maintains its recommendation to add the substance to the prohibited nonsynthetic list, that the NOP reconsider its proposal.

Delay in Review

OMRI notes the long delay in the response to the NOSB's recommendations. In at least one case the delay was nearly six years. All members of the NOSB involved in the original recommendation no longer serve. Any re-review of a longstanding recommendation would require considerable effort on the part of a current NOSB member. OMRI recommends that any future recommendations have their NOP review completed in a timely manner to minimize the loss of pertinent knowledge on the NOSB. The delay has also appeared to have resulted in misunderstandings on the part of producers, certifiers, the petitioners and suppliers as to the status of the substances. Clear, consistent, and timely responses are needed in order to avoid uncertainty.

Incorrect CAS Numbers

OMRI would like to point out that the *Federal Register* notice gives incorrect CAS numbers for bismuth subsalicylate and butorphanol. The CAS numbers published in the Merck Index are:

Bismuth subsalicylate 14882-18-9
Butorphanol 42408-82-2

Conclusion

OMRI urges the USDA to work with the FDA to resolve confusion and conflict between the National Organic Program Standards and the regulation of animal drugs. To do so, OMRI supports the NOSB's recommendation from February 28, 2005:

- 1) USDA and FDA should pursue further clarification at higher levels of USDA and FDA to facilitate co-existence of NOP and FDA regulatory processes for the listing of unapproved medications and other substances recommended by the NOSB.
- 2) NOP should pursue rulemaking to create a National List category in section 205.603 of "production aids" with reference to specific use.
- 3) USDA should investigate FDA recognition of "organic livestock production" as a "minor species/minor use" category.
- 4) NOP should review all recommended materials to more correctly place them in categories consistent with FDA regulation.

Because the viability of organic livestock producers and their animals' well-being are at stake, the matter is most urgent and requires immediate action, not another lengthy delay. OMRI also asks the NOP to immediately consult with the NOSB when conflicts with the FDA or other agencies arise over the NOSB's recommendations. The NOSB should be informed of the source of the conflict and should be able to communicate directly with designated contacts of the agency in question.

Sincerely,



Dave DeCou
Executive Director



Brian Baker
Research Director

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Table 2
Comparison of NOSB Recommendations,
NOP Proposals, and OMRI Comments for Livestock Materials

Material	NOSB Recommendation and Annotation	NOP Proposal	OMRI Comment
Activated Carbon (Activated Charcoal)	September 18, 2002 Synthetic, allowed from vegetative sources only.	Not proposed.	Add to 205.603(a) with the annotation: 'vegetative sources only subject to the discretion of the Food and Drug Administration.'
Atropine	May 14, 2003 Synthetic, allowed.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—51-55-8)—Federal law restricts this drug to use by or on the lawful order of a licensed veterinarian.	Add to 205.603(a) with the annotation '(CAS #—51-55-8)—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	September 18, 2002 Synthetic, allowed.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—14887-18-9)—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.	Add to 205.603(a) with the annotation '(CAS #—14882-18-9)—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	September 18, 2002 Synthetic, allowed. For use in organic livestock production with the following restrictions: withhold time shall be double the FDA requirements.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—14887-18-9)—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.	(CAS #—42408-82-2)—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. Use requires a withhold time of 42 days after administering to livestock intended for slaughter and 8 days after administering to dairy animals.
Calcium Borogluconate	November 16, 2000 Synthetic, allowed. For treatment of milk fever only.	Not proposed.	Add to 205.603(a) with the annotation "(CAS #—5743-34-0) Allowed for use at the discretion of the Food and Drug Administration for treatment of milk fever only."
Calcium Propionate	September 18, 2002 Synthetic, allowed. For milk fever only.	Not proposed for milk fever.	Add to 205.603(a) with the annotation "(CAS #—4075-81-4) For treatment of milk fever only, subject to the discretion of the Food and Drug Administration."
Calcium Propionate	May 14, 2003 Synthetic, allowed. As a mold inhibitor in dry formulated herbal remedies.	July 17, 2006 [71 FR 40632] 205.603(d)(1) (CAS #—4075-81-4)—For use only as a mold inhibitor in dry herbal products.	Petitioned / recommended use covered under the excipients policy [21 CFR 582.3221]. Do not add to 205.603(d). Should remain prohibited for use as a feed ingredient.
Epinephrine / Adrenaline	September 18, 2002 Nonsynthetic, prohibited. Except for emergency treatment of anaphylactic shock.	July 17, 2006 [71 FR 40632] Recommendation rejected.	Add to 205.604 with the annotation: '(CAS #—51-43-4) Except for emergency treatment of anaphylactic shock subject to the discretion of the Food and Drug Administration.'

Comparison of NOSB, NOP & OMRI Livestock Materials

Material	NOSB Recommendation and Annotation	NOP Proposal	OMRI Comment
Excipients	October 20, 2002 Synthetic, allowed. Excipients used in the manufacturing or found in the finished product of drugs used in livestock treatments are allowed unless specifically prohibited. [NOP considers the excipient to be approved by association with the active ingredient in an allowed drug formulation. Further regulatory clarification is expected in the upcoming 2004 Rule Docket.]	July 17, 2006 [71 FR 40632] 205.603(f) only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of New Animal Drug Application or New Drug Application.	Add to 205.603(f) with the annotation "only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of New Animal Drug Application or New Drug Application."
Flunixin	October 20, 2002 Synthetic, allowed. Withhold time shall be double the FDA requirement.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—38677-85-9)—in accordance with approved labeling.	Add to 205.603(a) with the annotation "(CAS #—38677-85-9)— Use requires a withhold time of 42 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals."
Furosemide	May 14, 2003 Synthetic, allowed. Withhold time shall be double the FDA requirement.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—54-31-9)—in accordance with approved labeling.	Add to 205.603(a) with the annotation "(CAS #—54-31-9)— Use requires a withhold time of 4 days after administering to livestock intended for slaughter and 4 days after administering to dairy animals."
Inert Ingredients	October 20, 2002 . . . [A]ny inert ingredients used in such pheromone formulations that are not on EPA List 1 (Inerts of toxicological concern) or EPA List 2 (Potentially toxic inerts), Provided the pheromone products are limited to passive dispensers. Pheromone products containing only pheromones, active ingredients listed in this section, and List 4 inerts may be applied without restriction.	Not Proposed	Add to 205.603(e) "as synthetic inert ingredients... (2) EPA -list 3 inerts of unknown toxicity, for use only in passive pheromone dispensers.
Ivermectin	November 17, 2000 Amend Rule annotation to add: slow release formulations such as the SR (slow release) bolus are prohibited.	Not proposed. April 16, 2003 docket renumbered as 205.603(a) (13).	Revise annotation at 205.603(a) to read: Add to 205.603(a) with the annotation "(CAS #—70288-86-7)— prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period of breeding stock. Slow release formulations are prohibited.
Kaolin Pectin	September 18, 2002 Synthetic, allowed. Allowed when formulated from either natural or synthetic pectin.	Not proposed.	These are two separate substances that are formulated in a brand name product. It is not necessary to add kaolin to the National List to have it allowed. Non-synthetic pectin is also currently allowed and synthetic pectin is on the National List at 205.605(b).

Comparison of NOSB, NOP & OMRI Livestock Materials

Material	NOSB Recommendation and Annotation	NOP Proposal	OMRI Comment
Magnesium Hydroxide	September 18, 2002 Synthetic, allowed. Allowed when formulated from either natural or synthetic materials.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—1309-42-8)—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.	Add to 205.603(a) with the annotation "(CAS #—1309-42-8)—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."
Magnesium Oxide	September 18, 2002 Synthetic, allowed. Allowed when formulated from either natural or synthetic materials.	Not proposed.	Add to 205.603(a) with the annotation "(CAS #—1309-48-4)—Subject to the discretion of the Food and Drug Administration."
Mineral Oil	September 18, 2002 Synthetic, allowed for healthcare.	Not proposed to 205.603(a) for internal use.	Add to 205.603(a) with the annotation "(CAS—# 8012-95-1) only for healthcare subject to the discretion of the Food and Drug Administration."
Moxidectin	April 29, 2004 Synthetic, allowed. Control of internal parasites only.	Not proposed.	Add to 205.603(a) with the annotation "(CAS #—113507-06-5)—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.
Peroxyacetic / peracetic Acid	November 16, 2000 Synthetic, allowed. For facility and processing equipment sanitation (barns, milking parlors, processing areas).	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—79-21-0)—For sanitizing facility and processing equipment.	Add to 205.603(a) with the annotation: "(CAS #—79-21-0)—For sanitizing facility and processing equipment."
Pheromones	October 20, 2002 Synthetic, allowed. Amend annotation to add: includes only EPA exempt pheromone products, EPA registered pheromone products with no additional toxicants unless listed in this section. . .	Not proposed.	Add to 205.603(b) with the annotation: "For insect management."
Poloxalene	March 6, 2001 Synthetic, allowed. For emergency treatment of bloat.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—9003-11-6)—in accordance with approved labeling.	Add to 205.603(a) with the annotation "(CAS #—9003-11-6)—for emergency treatment of bloat."
Potassium Sorbate	September 18, 2002 Synthetic, allowed. Only for use in Aloe Vera products.	Not proposed.	Petitioned / recommended use covered under the excipients policy [21 CFR 582.3662].
Propylene Glycol	September 19, 2002 Synthetic, allowed. Only for treatment of acute ketosis in ruminants.	Not proposed.	Add to 205.603(a) with the annotation "(CAS #—57-55-6)—Only for treatment of acute ketosis in ruminants subject to the discretion of the Food and Drug Administration."
Tolazoline	September 19, 2002 Synthetic, allowed. To counteract the effects of xylazine, withhold time shall be double FDA requirements.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—59-98-3)—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	Add to 205.603(a) with the annotation "(CAS #—59-98-3)—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

Comparison of NOSB, NOP & OMRI Livestock Materials

Material	NOSB Recommendation and Annotation	NOP Proposal	OMRI Comment
		the Food and Drug Administration regulations.	Administration regulations. Use requires a withhold time of 8 days after administering to livestock intended for slaughter and 4 days after administering to dairy animals.
Xylazine	September 19, 2002 Synthetic, allowed. For emergency use only, withhold time shall be double FDA requirement.	July 17, 2006 [71 FR 40632] 205.603(a)(22) (CAS #—7361-61-7)—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.	Add to 205.603(a) with the annotation "(CAS #—7361-61-7)—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. Use requires a withhold time of 8 days after administering to livestock intended for slaughter and 4 days after administering to dairy animals.

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