DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[Docket Number TM–03–04]

RIN 0581–AC62

National Organic Program (NOP); Proposed Amendments to the National List of Allowed and Prohibited Substances (Livestock)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) regulations to reflect recommendations submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) from October 30, 2000, through March 3, 2005. Consistent with the recommendations from the NOSB, this proposed rule would add thirteen substances, along with any restrictive annotations, to the National List.

DATES: Comments must be received by September 15, 2006.

ADDRESSES: Interested persons may comment on this proposed rule using the following procedures:

- *Mail:* Comments may be submitted by mail to: Arthur Neal, Director of Program Administration, National Organic Program, USDA–AMS–TMP–NOP, 1400 Independence Ave., SW., Room 4008–So., Ag Stop 0268, Washington, DC 20250.
- *E-mail:* Comments may be submitted via the Internet to: *National.List@usda.gov.*
- *Internet: www.regulations.gov.*
- *Fax:* Comments may be submitted by fax to: (202) 205–7808.
- Written comments on this proposed rule should be identified with the docket number TM–03–04. Commenters should identify the topic and section number of this proposed rule to which the comment refers.
- Clearly indicate if you are for or against the proposed rule or some portion of it and your reason for it. Include recommended language changes as appropriate.
- Include a copy of articles or other references that support your comments. Only relevant material should be submitted.

It is our intention to have all comments to this proposed rule, whether submitted by mail, e-mail, or fax, available for viewing on the NOP homepage. Comments submitted in response to this proposed rule will be available for viewing in person at USDA–AMS, Transportation and Marketing, Room 4008–South Building, 1400 Independence Ave., SW., Washington, DC, from 9 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposed rule are requested to make an appointment in advance by calling (202) 720–3252.

FOR FURTHER INFORMATION CONTACT: Arthur Neal, Director of Program Administration, Telephone: (202) 720–3252; Fax: (202) 205–7808.

SUPPLEMENTARY INFORMATION:

I. Background.

On December 21, 2000, the Secretary established, within the NOP [7 CFR part 205], the National List regulations (§§ 205.600 through 205.607). The National List regulations identify synthetic substances and ingredients that are allowed and nonsynthetic (natural) substances and ingredients that are prohibited for use in organic production and handling. Under the authority of the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), the National List can be amended by the Secretary based on proposed amendments developed by the NOSB. Since established, the National List has been amended three times, October 31, 2003 (68 FR 61987), November 3, 2003 (68 FR 62215), and October 21, 2005 (70 CFR 61217). Additionally, an amendment to the National List, proposed on September 16, 2005 (70 FR 54660), is currently pending.

This proposed rule would amend the National List to reflect recommendations submitted to the Secretary by the NOSB from November 15, 2000, through March 3, 2005. Between the specified time period, the NOSB has recommended that the Secretary add thirteen substances to § 205.603 and one substance to §1A205.604 of the National List regulations.

II. Overview of Proposed Amendments.

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

Section 205.603 Synthetic substances allowed for use in organic livestock production.

This proposed rule would amend paragraph (a) of § 205.603 of the National List regulations by adding the following substances:

Atropine (CAS #—51–55–8). Atropine was petitioned for use in organic livestock production as an antidote for organophosphate poisoning usually caused by reactions to pesticides. Atropine is an anti-cholinergic drug that is derived from the plant *atropa belladonn.* It is a white, odorless crystalline powder that causes a reduction in salivary, bronchial, and sweat gland secretions, which makes it useful as an anesthetic.

At its May 13–14, 2003, meeting in Austin, TX, the NOSB recommended adding atropine to the National List for use in organic livestock as a medical treatment. In this open meeting, the NOSB evaluated atropine against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that atropine is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) to ensure that the recommendation for atropine would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that atropine is permitted for use in cattle, goats, horses, pigs, sheep, cats and dogs under 21 CFR 500.55, with use limitations. The NOP further learned that Federal law restricts atropine to use by or on the lawful written or oral order of a licensed veterinarian.

Concerning the use of atropine, the EPA deferred to FDA as the appropriate regulatory body. Therefore, regarding organic livestock production, the use of atropine would be considered permissible under the FDA regulations, if used in accordance with the FDA restrictions. As a result, the Secretary is proposing to accept the NOSB's recommendation for atropine and amend § 205.603(a) of the National List by adding atropine as a medical treatment in livestock production as follows:

Atropine (CAS #—51–55–8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian.

Bismuth subsalicylate (CAS #—14887–18–9). Bismuth subsalicylate was petitioned for use in organic livestock production as an adsorbent, anti-diarrhea aid, and relief for ulcers. It is a white, odorless powder that is almost insoluble in water and decomposes in boiling water.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB

recommended adding bismuth subsalicylate to the National List for use in organic livestock production as a veterinary treatment. In this open meeting, the NOSB evaluated bismuth subsalicylate against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the substance is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for bismuth subsalicylate would be consistent with federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that bismuth subsalicylate is approved as a drug for use in humans (FDA, ''Approved Drug Products with Therapeutic Equivalence Evaluations, 2005''.) New Animal Drug Application approvals for bismuth subsalicylate were not identified. However, the NOP learned that bismuth subsalicylate could be permitted for use in livestock production if used in full compliance with the Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) and 21 CFR part 530 of the FDA regulations, ''Provision permitting extra-label use of animal drugs.'' The AMDUCA and 21 CFR part 530 allow the extra-label use of approved new animal drugs or human drugs by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship.

Concerning the use of bismuth subsalicylate, the EPA deferred to FDA as the appropriate regulatory body. As a result, regarding organic livestock production, the only way that bismuth subsalicylate could be considered permissible under the FDA regulations and recommended for inclusion on the National List is under the provisions of the AMDUCA and 21 CFR part 530 of the FDA regulations. Otherwise, the Secretary would not be able accept the NOSB's recommendation to include bismuth subsalicylate on the National List. Thus, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding bismuth subsalicylate as a medical treatment in livestock production as follows:

Bismuth subsalicylate (CAS #—14887–18–9)—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.

Butorphanol (CAS #—14887–18–9). Butorphanol was petitioned for use in organic livestock production as a pain reliever to be administered prior to surgery and under veterinary care. Butorphanol is a clear, colorless, and odorless liquid. It is most often found as butorphanol tartrate, an injectable form of the substance. Butorphanol belongs to a general class of drugs known as opiate agonists. Other related drugs in this class include buprenorphine, fentanyl, meperidine and morphine. Butorphanol has significant pain control and sedation properties, but it does not last long. Butorphanol is a controlled drug and is only available through veterinarians with an active Drug Enforcement Administration license.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding butorphanol on the National List for use in organic livestock production, with the restriction that that the withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated butorphanol against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the substance is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for butorphanol would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that butorphanol is approved as a drug for use in dogs, cats, and horses (21 CFR 522.246), with use limitations. New Animal Drug Application approvals for its use in cattle were not identified. However, the NOP learned that butorphanol could be permitted for use in livestock production if used in full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations, ''Provision permitting extra-label use of animal drugs.'' The AMDUCA and 21 CFR part 530 allow the extra-label use of approved new animal drugs or human drugs by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship.

Concerning the use of butorphanol, the EPA deferred to FDA as the appropriate regulatory body. As a result, regarding organic livestock production, the only way that butorphanol could be considered permissible under the FDA regulations and recommended for inclusion on the National List is under the provisions of the AMDUCA and 21 CFR part 530 of the FDA regulations. Otherwise, the Secretary could not accept the NOSB's recommendation to include butorphanol on the National List.

The Secretary acknowledges the NOSB's recommendation to restrict the use of butorphanol by extending the withdrawal period twice beyond what the FDA requires. However, the Secretary does not accept the recommended restriction. The recommended restriction to extend the withdrawal period twice beyond what the FDA requires would create an additional label claim for the animal drug beyond that which is permitted by the FDA. Therefore, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding butorphanol as a medical treatment in livestock production as follows:

Butorphanol (CAS #—14887–18–9)—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.

Flunixin (CAS #—38677–85–9). Flunixin was petitioned for use in organic livestock production to treat inflammation and pyrexia. Flunixin is a non-narcotic, nonsteroidal analgesic agent with anti-inflammatory and antipyretic activity. It is a synthetic drug more commonly made into flunixin meglumine, which is the primary component of an injectable flunixin solution. It is administered intravenously and intramuscularly, quickly broken down internally, and cleared from the bloodstream in urine.

At its October 19–20, 2002, meeting in Washington, DC, the NOSB recommended adding flunixin on the National List as an allowed synthetic in organic livestock production, with the restriction that the withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated flunixin against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for flunixin would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that flunixin is listed at 21 CFR 520.970 and 522.970, with use and labeling limitations, as an FDA approved animal drug for horses, cattle, and swine. Regarding organic livestock production, the NOP learned that the use of flunixin would be considered permissible under the FDA regulations for approved species.

Concerning the use of flunixin, the EPA deferred to FDA as the appropriate regulatory body. Therefore, after consulting with the FDA and EPA about the use of flunixin in organic livestock production, the Secretary is proposing to accept the NOSB recommendation to add flunixin to the National List. However, the Secretary does not accept the recommended restriction to extend the withdrawal period twice beyond what the FDA requires. The recommended use restriction to extend the withdrawal period twice beyond the FDA required withdrawal period would create an additional label claim for the animal drug beyond that which is permitted by the FDA.

Therefore, the Secretary is proposing to amend § 205.603(a) of the National List by adding flunixin as a medical treatment in livestock production as follows:

Flunixin (CAS #—38677–85–9)—in accordance with approved labeling.

Furosemide (CAS #—54–31–9). Furosemide was petitioned for use in organic livestock production as a livestock medical treatment for udder and pulmonary edema. Furosemide is a diurectic. It is a white or slightly yellow crystalline powder that is odorless. Furosemide is practically insoluble in water, sparingly soluble in alcohol, freely soluble in alkali solutions, and insoluble in dilute acids.

At its May 13–14, 2003, meeting in Austin, Texas, the NOSB recommended adding furosemide on the National List for use in organic livestock production, with the restriction that the withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated furosemide against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for furosemide would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that furosemide is listed at 21 CFR 520.1010 and 522.1010, with use and labeling limitations, as allowed for use in treating dogs, cats, horses, and cattle. Regarding organic livestock production, the NOP learned that the use of furosemide would be considered permissible under the FDA regulations for approved species.

Concerning the use of furosemide, the EPA deferred to FDA as the appropriate regulatory body. Therefore, after consulting with the FDA and EPA about the use of furosemide in organic livestock production, the Secretary is proposing to accept the NOSB recommendation to add furosemide to the National List. However, the Secretary does not accept the recommended restriction to extend the withdrawal period twice beyond what the FDA requires. The recommended use restriction to extend the withdrawal period twice beyond the FDA required withdrawal period would create an additional label claim for the animal drug beyond that which is permitted by the FDA. Therefore, the Secretary is proposing to amend § 205.603(a) of the National List by adding furosemide as a medical treatment in livestock production as follows:

Furosemide (CAS #—54–31–9)—in accordance with approved labeling.

Magnesium hydroxide (CAS #—1309–42–8). Magnesium hydroxide was petitioned for use in organic livestock production as an antacid and laxative for temporary relief of an upset stomach and constipation. Magnesium hydroxide (brucite) is found naturally in serpentine, chlorite or dolomitic schists, or in crystalline limestones as an alteration product of periclase (magnesium oxide). It is prepared by mixing sodium hydroxide with a water-soluble magnesium salt. It is also formed by the hydration of reactive magnesium oxide. Magnesium hydroxide is mainly used in antacid or laxative tablets. Antacids are used to relieve minor stomach pain, heartburn, and hyperacidity.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding magnesium hydroxide to the National List as a synthetic substance allowed for use in organic livestock production. In this open meeting, the NOSB evaluated magnesium hydroxide against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for magnesium hydroxide would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that magnesium hydroxide is approved as a drug for use in humans (FDA, ''Approved Drug Products with Therapeutic Equivalence Evaluations, 2005''.) New Animal Drug Application approvals for its use in livestock were not identified. However, the NOP learned that magnesium hydroxide could be permitted for use in livestock production if used in full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations, ''Provision permitting extra-label use of animal drugs.'' The AMDUCA and 21 CFR part 530 allow the extra-label use of approved new animal drugs or human drugs by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship.

Concerning the use of magnesium hydroxide, the EPA deferred to FDA as the appropriate regulatory body. As a result, regarding organic livestock production, the only way that magnesium hydroxide could be considered permissible under the FDA regulations and recommended for inclusion on the National List is under the provisions of the AMDUCA and 21 CFR part 530 of the FDA regulations. Otherwise, the Secretary would not be able to accept the NOSB's recommendation to include magnesium hydroxide on the National List. Thus, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding magnesium hydroxide as a medical treatment in livestock production as follows:

Magnesium hydroxide (CAS #—1309–42–8)—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.

Peroxyacetic/Peracetic acid (CAS #—79–21–0). Peracetic acid was petitioned for use in organic livestock production for facility and processing equipment sanitation. Peracetic acid is a mixture of acetic acid and hydrogen peroxide in an

aqueous solution. It is liquid, clear, and colorless with no foaming capability. Peracetic acid is primarily used to clean equipment, milking parlors, barns, stalls, and veterinary facilities. It is also used as a topical disinfectant on animals and in the handling and processing of livestock products as a dairy equipment sanitizer, meat and poultry disinfectant, and egg wash.

At its November 15–17, 2000, meeting in Washington, DC, the NOSB recommended adding peracetic acid to the National List as a synthetic substance allowed for sanitizing facility and processing equipment (e.g. barns, milking parlors, and processing areas) in organic livestock production. In this open meeting, the NOSB evaluated peracetic acid against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for peracetic acid would be consistent with the FDA regulations concerning the approved use of the substance. Based on consultations with FDA, the NOP was informed that peracetic acid (also recognized as peroxyacetic acid and has the same Chemical Abstract System Registration number, 79–21–0) is approved by the FDA as an indirect food additive and sanitizing solution under 21 CFR 178.1010(b)(30). Concerning the use of peracetic acid, the EPA deferred to FDA as the appropriate regulatory body. As a result, the Secretary is proposing to amend § 205.603(a) by adding peracetic acid as a sanitizer in livestock production as follows:

Peroxyacetic/peracetic acid (CAS #—79–21–0)—for sanitizing facility and processing equipment.

Poloxalene (CAS #—9003–11–6). Poloxalene was petitioned for use in organic livestock production for the treatment of bloat in cattle. Poloxalene is a copolymer of polyethylene and polypropylene ether glycol. It is a non-ionic polyol surface-active agent used as a fecal softener and preventive bloat treatment in cattle. Poloxalene may be administered as a drench (orally through a tube), preventively fed in a molasses block, and as a top dressing for feed (21 CFR 520.1840).

At its March 6–7, 2001, meeting in Washington, DC, the NOSB recommended adding poloxalene to the National List as a synthetic substance allowed for use in organic livestock production, with the restriction that it only be used for the emergency treatment of bloat (not routine use). In this open meeting, the NOSB evaluated poloxalene against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for poloxalene would be consistent with Federal regulations concerning the approved use of the substance. Based on consultations with the FDA, the NOP was informed that poloxalene is approved for the treatment of bloat in cattle (21 CFR 520.1840 and 558.464). The NOP further learned that, regarding organic livestock production, poloxalene would be considered permissible under the FDA regulations.

Concerning the use of poloxalene, the EPA deferred to FDA as the appropriate regulatory body. As a result, the Secretary is proposing to accept the NOSB's recommendation to add poloxalene to the National List. However, the Secretary does not accept the recommended restriction that poloxalene only be used for the emergency treatment of bloat. The Secretary acknowledges the NOSB's intent to limit the use of poloxalene in organic livestock production, but the recommended use restriction would create an additional label claim for the animal drug that has not been evaluated under an FDA New Animal Drug Application. Any prescriptive uses of poloxalene codified by the USDA would have to be evaluated under an FDA New Animal Drug Application. USDA does not have the authority to prescribe or restrict uses of animal drugs outside of what is already approved, permitted, or restricted under the FDA regulations. As a result, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding poloxalene as a medical treatment in livestock production as follows:

Poloxalene (CAS #—9003–11–6)—in accordance with approved labeling.

Tolazoline (CAS #—59–98–3). Tolazoline was petitioned for use in organic livestock production as a medical treatment. Tolazoline is a white to off-white crystalline powder that is freely soluble in water and alcohol. It is used as a medical treatment in both humans and animals. Tolazoline has direct actions on blood vessels by decreasing the pulmonary arterial pressure and peripheral resistance, and increasing venous capacitance and cardiac output. In horses, tolazoline is used to reverse the sedative/analgesic effects of xylazine hydrochloride during surgery.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding tolazoline to the National List as a synthetic substance to be allowed for use in organic livestock production, with the restrictions that it: (1) Only be used to counteract the effects of xylazine; and (2) carry a withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated tolazoline against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for tolazoline would be consistent with Federal regulations concerning the approved use of the substance. Based on consultations with the FDA, the NOP was informed that tolazoline hydrochloride injection is approved for use in horses and does not have an established withdrawal period (21 CFR 522.2474). The NOP also learned that tolazoline does not have an approved use for food producing animals. However, the NOP discovered that tolazoline could be permitted for use in food animals if used in full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations, ''Provision permitting extra-label use of animal drugs.'' The AMDUCA and 21 CFR part 530 of the FDA regulations allow the extra-label use of approved new animal drugs or human drugs by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship.

Concerning the use of tolazoline, the EPA deferred to FDA as the appropriate regulatory body. As a result, regarding organic livestock production, the only way that tolazoline could be considered permissible for food producing animals under the FDA regulations and recommended for inclusion on the National List is under the provisions of the AMDUCA and 21 CFR part 530 of the FDA regulations. Otherwise, the Secretary would not be able to accept the NOSB's recommendation to include tolazoline on the National List for food producing livestock.

The Secretary acknowledges the NOSB's recommendation to restrict the use of tolazoline to only be used for counteracting the effects of xylazine. The Secretary also recognizes the NOSB's recommendation to restrict the use of tolazoline by extending the withdrawal period twice beyond what the FDA requires. However, the Secretary does not accept the recommended restrictions. Users must understand that to be used in organic livestock production, tolazoline would have to be administered under full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations. Any prescriptive uses of this drug codified by the USDA have to be evaluated under an FDA New Animal Drug Application. USDA does not have the authority to prescribe or restrict uses of animal drugs outside of what is already approved, permitted, or restricted under the FDA regulations. To do so would create an additional label claim for the animal drug beyond that which is permitted by the FDA. Therefore, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding tolazoline as a medical treatment in livestock production as follows:

Tolazoline (CAS #—59–98–3)—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.

Xylazine (CAS #—7361–61–7). Xylazine was petitioned for use in organic livestock production as a medical treatment. Xylazine is a white or almost white crystalline substance that is freely soluble in water. It is used as a sedative, analgesic, and muscle relaxant in veterinary medicine. Administration of tolazoline reverses xylazine's effects, resulting in rapid recovery from sedation.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding xylazine to the National List as a synthetic substance to be allowed for use in organic livestock production, with the restrictions that it: (1) Be for emergency use only; and (2) carry a withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated xylazine against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for xylazine would be consistent with federal regulations concerning the approved use of the substance. Based on consultations with the FDA, the NOP was informed that xylazine hydrochloride is approved for use in cats, dogs, horses, elk, and deer. The NOP also learned that xylazine hydrochloride does not have an approved use for food producing animals (21 CFR 522.2662). However, the NOP was informed that xylazine could be permitted for use in food producing animals if used under full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations, ''Provision permitting extra-label use of animal drugs.'' The AMDUCA and 21 CFR part 530 of the FDA regulations allow the extra-label use of approved new animal drugs or human drugs by or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship.

Concerning the use of xylazine, the EPA deferred to FDA as the appropriate regulatory body. As a result, regarding organic livestock production, the only way that xylazine could be considered permissible for food producing animals under the FDA regulations and recommended for inclusion on the National List is under the provisions of the AMDUCA and 21 CFR part 530 of the FDA regulations. Otherwise, the Secretary would not be able to accept the NOSB's recommendation to include xylazine on the National List for food producing livestock.

The Secretary acknowledges the NOSB's recommendation to restrict the use of xylazine for emergency use only. The Secretary also recognizes the NOSB's recommendation to restrict the use of tolazoline by extending the withdrawal period twice beyond what the FDA requires. However, the Secretary does not accept the recommended restrictions. Users must understand that to be used in organic livestock production, xylazine would have to be administered under full compliance with the AMDUCA and 21 CFR part 530 of the FDA regulations. Any prescriptive uses of this drug codified by the USDA have to be evaluated under an FDA New Animal Drug Application. USDA does not have the authority to prescribe or restrict uses of animal drugs outside of what is already approved, permitted, or restricted under the FDA regulations. To do so would create an additional label claim for the animal drug beyond that which is permitted by the FDA. Therefore, after consulting with the FDA and EPA, the Secretary is proposing to amend § 205.603(a) of the National List by adding xylazine as a medical treatment in livestock production as follows:

Xylazine (CAS #—7361–61–7)—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.

This proposed rule would amend § 205.603(d) of the National List regulations by adding the following substance:

Calcium propionate (CAS #—4075–81–4). Calcium propionate was petitioned for use in organic livestock production as a mold inhibitor in dry formulated herbal products. Calcium propionate is a white powder that is soluble in water and stable under ordinary conditions. It is used in the food and feed industry as a preservative and has effective antimicrobial characteristics.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding calcium propionate onto the National List for use in organic livestock production as a mold inhibitor in dry herbal products. In this open meeting, the NOSB evaluated calcium propionate against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the substance is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for calcium propionate would be consistent with Federal regulations concerning the use of feed additives. Based on consultations with the FDA, the NOP was informed that calcium propionate is allowed for use as a feed additive under 21 CFR 582.3221. Concerning the use of calcium propionate, the EPA deferred to FDA as the appropriate regulatory body. As a result, the Secretary is proposing to amend § 205.603(d) of the National List by adding calcium propionate as a feed additive for use in livestock production as follows:

Calcium propionate (CAS #—4075–81–4)—for use only as a mold inhibitor in dry herbal products.

This proposed rule would amend § 205.603 of the National List

regulations by adding a new paragraph (f) and adding the following substance:

Excipients. Excipients are defined by the FDA as any inactive ingredients that are intentionally added to therapeutic and diagnostic products, but that are: (1) Not intended to exert therapeutic effects at the intended dosage, although they may act to improve product delivery (*e.g.*, enhance absorption or control release of the drug substance); and (2) not fully qualified by existing safety data with respect to the currently proposed level of exposure, duration of exposure, or route of administration. Examples of excipients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents (FDA ''Guidance for Industry Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients, May 2005'').

Through the evaluation of several active ingredients that had been petitioned for inclusion on the National List, the NOSB recognized that inactive ingredients (excipients) in medications pose one of the most problematic examples of the use of synthetic materials in organic livestock production. With respect to synthetic excipients and the verification of their inclusion in medications, it is difficult for farmers or certifying agents to identify specific excipients utilized in medications because federal law does not require excipients to appear on ingredient labels of products. In addition, identifying the use of excipients becomes challenging because product manufacturers typically treat product formulas as confidential information. As a result, a petitioner's ability to petition the NOSB to evaluate a specific excipient of a certain product formulation for inclusion on the National List becomes increasingly complicated and burdensome.

Considering the practical challenges posed by the use of excipients in medications for livestock animals, the NOSB decided to develop a recommendation that would bring a balance between standard practice and strict statutory requirements concerning the use of synthetic ingredients in organic livestock production (synthetic substances can only be used in organic production as long as they appear on the National List). The NOSB recognized that petitioners would not have any difficulty petitioning individual active synthetic ingredients intended for use as livestock medications. However, the NOSB also acknowledged the problems associated with correctly identifying excipient-active ingredient combinations/formulations and the consequences of not having appropriate excipients listed on the National List for use in combination with approved active synthetic ingredients (producers could be applying synthetic substances not allowed for use in organic production without proper knowledge).

As a result, at its October 19–20, 2002, meeting in Washington, DC, the NOSB recommended the creation of a new paragraph under § 205.603 that would recognize the categorical use of excipients utilized in the manufacturing or found in the finished product of drugs used to treat organic livestock. In recognizing the categorical use of excipients found in drugs used to treat organic livestock, the NOSB also recommended that excipients that are specifically prohibited on the National List would not be allowed for use in drugs used to treat organic livestock.

The NOP engaged in consultations with the FDA and EPA to ensure that the NOSB recommendation concerning the use of excipients would be consistent with federal regulations concerning the approved uses for the category of substances. Based on our consultations with the FDA, the NOP was informed that excipients are allowed for use in the manufacture of human and animal drugs. In addition, the FDA informed the NOP that not all excipients are inert substances; some have been shown to be potential toxicants. As a result, the FDA recommended that the NOP consider acknowledging the use of excipients that are: (1) Identified by the FDA as Generally Recognized As Safe (GRAS); (2) approved by the FDA as a food additive; or (3) included in the FDA review and approval of New Animal Drug Applications and New Drug Applications.

Concerning the use of excipients, the EPA deferred to FDA as the appropriate regulatory body. As a result, the Secretary is proposing to amend § 205.603 by adding a new paragraph (f) and recognizing excipients as allowed substances in the manufacture of drugs used to treat organic livestock as follows:

(f) Excipients, 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 a New Animal Drug Application or New Drug Application.

Recommendations Not Accepted

Epinephrine (CAS #—51–43–4). Epinephrine was petitioned for use in organic livestock production as a treatment for anaphylactic shock. Epinephrine is a naturally derived hormone that is secreted from the adrenal glands as part of the sympathetic nervous system in mammals. As a medical drug, epinephrine is used to stimulate heartbeat and to treat emphysema, bronchitis, bronchial asthma and other allergic conditions.

At its September 17–19, 2002, meeting in Washington, DC, the NOSB recommended adding epinephrine to § 205.604 of the National List as a prohibited natural in organic livestock production, with the restrictions that it: (1) Only be allowed for the emergency treatment of anaphylactic shock; and (2) carry a withdrawal period (the interval between the time of the last administration of a sponsored compound and the time when the animal can be safely slaughtered for food or the milk can be safely consumed) for use of the substance be extended twice beyond what would be required by the FDA. In this open meeting, the NOSB evaluated epinephrine against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the general use of epinephrine in organic livestock production is not consistent with the OFPA evaluation criteria and should be restricted because it is a hormone. The OFPA states that for a farm to be certified as an organic farm, with respect to the livestock produced by the farm, producers shall not use growth promoters and hormones on livestock, whether implanted, ingested, or injected (7 U.S.C. 6509(c)(3)).

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for epinephrine would be consistent with Federal regulations concerning the use of animal drugs. Based on consultations with the FDA, the NOP was informed that epinephrine is listed at 21 CFR 500.65, with use and labeling limitations, as the emergency treatment for anaphylactic shock in cattle, horses, sheep, and swine. The NOP also learned that epinephrine, when used in animals, cannot be used outside of the provisions of 21 CFR 500.65. Concerning the use of epinephrine, the EPA deferred to FDA as the appropriate regulatory body.

In review of the NOSB recommendation for restricting the use of epinephrine and the information gathered through consultation with the FDA, we believe that the intent of the NOSB's recommendation is already satisfied through the FDA restrictions on the use of epinephrine in livestock

production. We believe that listing epinephrine at § 205.604 as a ''nonsynthetic substance prohibited for use in organic livestock production'' would be confusing to users of the National List. Since epinephrine is a non-synthetic substance, currently allowed in organic production, and restricted ''for emergency use only'' under the FDA regulations, further restriction under the NOP regulations is not necessary. As a result, the Secretary is proposing not to accept the NOSB recommendation to add epinephrine to § 205.604 of the National List as a ''nonsynthetic substance prohibited for use in organic livestock production.''

Moxidectin (CAS #—113507–06–5). Moxidectin was petitioned for use in organic livestock production as a medical treatment for controlling internal and external parasites. Moxidectin is a macrolide antibiotic that is chemically synthesized from nemadectin, an antibiotic produced in the fermentation of streptomyces cyaneogriseus sp. noncyanogenus. Moxidectin is effective against gastrointestinal roundworms, lungworms, cattle grubs, mites, lice and horn flies. Although moxidectin is a macrolide antibiotic, it was petitioned for use as a parasiticide.

At its April 28–30, 2004, meeting in Chicago, IL, the NOSB recommended adding moxidectin to the National List, with the restriction that it only be allowed for use to control internal parasites. In this open meeting, the NOSB evaluated moxidectin against the evaluation criteria of 7 U.S.C. 6517 and 6518 of the OFPA, received public comment, and concluded that the use of the substance in organic livestock production is consistent with the OFPA evaluation criteria.

The NOP engaged in consultations with the FDA and EPA to ensure that the recommendation for moxidectin would be consistent with the federal regulations concerning the approved use of the substance. Based on consultations with the FDA, the NOP was informed that moxidectin is approved for use by the FDA for treatment and control of internal and external parasites in beef and dairy cattle (21 CFR 524.1451). Concerning the use of moxidectin, the EPA deferred to FDA as the appropriate regulatory body.

Although moxidectin is approved for use in beef and dairy cattle by the FDA, the Secretary cannot accept the NOSB's recommendation to add moxidectin to the National List because it is a macrolide antibiotic. The Secretary received a recommendation from the NOSB, during its October 12–14, 2004, meeting to clarify that antibiotics are not allowed for the production of organic animals or edible organic products once a producer is certified organic. The Secretary accepted this recommendation and issued the recommended clarification on April 22, 2005 (*http://www.ams.usda.gov/nop/NOP/PolicyStatements/USDANOSBFeedback3_10_05.pdf*). The Secretary acknowledges that moxidectin has been petitioned for use as a parasiticide, however, the Secretary cannot overlook the fact that moxidectin is a macrolide antibiotic. Due to this fact, the Secretary cannot accept the NOSB recommendation to permit the use of moxidectin in organic livestock production.

Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol. The NOSB made six recommendations to the Secretary regarding the inclusion of activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, and propylene glycol as substances that should be allowed for use as veterinary treatments in organic livestock production. Based on consultations with the FDA, the NOP was informed that those substances were not approved by the FDA for use in cattle and would not qualify for extra-label use by a licensed veterinarian under the AMDUCA. The EPA deferred to FDA as the appropriate regulatory body for the use of the substances. As a result, the Secretary, at this time, cannot accept the recommendations to allow the use of those six substances under § 205.603, as livestock medications. The Secretary remains in consultation concerning the use of these six substances in organic livestock production. However, until otherwise notified by the Secretary, synthetic activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, and propylene glycol will remain prohibited for use in organic livestock production.

III. Related Documents

Six notices were published regarding the meetings of the NOSB and its deliberations on recommendations and substances petitioned for amending the National List. Substances and recommendations included in this proposed rule were announced for NOSB deliberation in the following **Federal Register** Notices: (1) 65 FR 64657, October 30, 2000, (Calcium borogluconate); (2) 66 FR 10873, February 20, 2001, (Poloxalene); (3) 67 FR 54784, August 26, 2002, (Activated charcoal, Bismuth subsalicylate, Butorphanol, Epinephrine, Kaolin pectin, Magnesium hydroxide, Potassium sorbate, Propylene glycol, Tolazoline, and Xylazine); (4) 67 FR 62949, October 9, 2002, (Excipients and Flunixin); (5) 68 FR 23277, May 1, 2003, (Atropine, Calcium propionate, Furosemide, and Mineral oil); and (6) 69 FR 18036, April 6, 2004, (Moxidectin).

IV. Statutory and Regulatory Authority

The OFPA, as amended (7 U.S.C. 6501 *et seq.*), authorizes the Secretary to make amendments to the National List based on proposed amendments developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop proposed amendments to the National List for submission to the Secretary and establish a petition process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. The National List petition process is implemented under § 205.607 of the NOP regulations. The current petition process (65 FR 43259) can be accessed through the NOP Web site at *http://www.ams.usda.gov/nop*.

A. Executive Order 12866

This action has been determined not significant for purposes of Executive Order 12866, and therefore, has not been reviewed by the Office of Management and Budget.

B. Executive Order 12988

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under section 2115 of the OFPA (7 U.S.C. 6514) from creating programs of accreditation for private persons or State officials who want to become certifying agents of organic farms or handling operations. A governing State official would have to apply to USDA to be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the

production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120(f) of the OFPA (7 U.S.C. 6519(f)), this proposed rule would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000 (65 FR 80548). The AMS has also considered the economic impact of this action on small entities. The impact on entities affected by this proposed rule would not be significant. The effect of this proposed rule would be to allow the use of additional substances in agricultural production and handling. This action would relax the regulations published in the final rule and would provide small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, would be minimal and entirely beneficial to small agricultural service firms. Accordingly, USDA certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than $6,500,000 and small agricultural producers are defined as those having annual receipts of less than $750,000. This proposed rule would have an impact on a substantial number of small entities.

The U.S. organic industry at the end of 2001 included nearly 6,949 certified organic crop and livestock operations. These operations reported certified acreage totaling more than 2.09 million acres of organic farm production. Data on the numbers of certified organic handling operations (any operation that transforms raw product into processed products using organic ingredients) were not available at the time of survey in 2001; but they were estimated to be in the thousands. By the end of 2004, the number of certified organic crop, livestock, and handling operations totaled nearly 11,400 operations. Based on 2003 data, certified organic acreage increased to 2.2 million acres.

U.S. sales of organic food and beverages have grown from $1 billion in 1990 to an estimated $12.2 billion in 2004. Organic food sales are projected to reach $14.5 billion for 2005; total U.S. organic sales, including nonfood uses, are expected to reach $15 billion in 2005. The organic industry is viewed as the fasting growing sector of agriculture, representing 2 percent of overall food and beverage sales. Since 1990, organic retail sales have historically demonstrated a growth rate between 20 to 24 percent each year. This growth rate is projected to decline and fall to a rate of 5 to 10 percent in the future.

In addition, USDA has accredited 96 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at *http://www.ams.usda.gov/nop.* AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Under the OFPA, no additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by section 350(h) of the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

AMS is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible.

E. General Notice of Public Rulemaking

This proposed rule reflects recommendations submitted to the Secretary by the NOSB. The 13 substances proposed to be added to the National List were based on petitions from the industry. The NOSB evaluated each petition using criteria in the OFPA. Because these substances are critical to organic production and handling operations, producers and handlers should be able to use them in their operations as soon as possible. A 60-day period for interested persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205.

Administrative practice and procedure, Agriculture, Animals, Archives and records, Imports, Labeling, Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation.

For the reasons set forth in the preamble, 7 CFR part 205, Subpart G is proposed to be amended as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 continues to read as follows:

Authority: 7 U.S.C. 6501–6522.

2. Section 205.603 is revised to read as follows:

§ 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

(a) As disinfectants, sanitizer, and medical treatments as applicable.

(1) Alcohols (Ethanol-disinfectant and sanitizer only, prohibited as a feed additive; and Isopropanol-disinfectant only.)

(2) Aspirin-approved for health care use to reduce inflammation.

(3) *Atropine (CAS #—51–55–8)*—Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian.

(4) *Biologics*—Vaccines.

(5) *Bismuth subsalicylate (CAS #—14887–18–9)*—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 Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.

(6) *Butorphanol (CAS #—14887–18–9)*—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 Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.

(7) *Chlorhexidine*—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.

(8) *Chlorine materials*—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite.)

(9) *Electrolytes*—without antibiotics.

(10) *Flunixin (CAS #—38677–85–9)*—in accordance with approved labeling.

(11) *Furosemide (CAS #—54–31–9)*—in accordance with approved labeling.

(12) Glucose.

(13) *Glycerine*—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(14) Hydrogen peroxide.

(15) Iodine.

(16) *Magnesium hydroxide (CAS #—1309–42–8)*—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 Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.

(17) Magnesium sulfate.

(18) *Oxytocin*—use in postparturition therapeutic applications.

(19) Paraciticides. *Ivermectin*—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 for breeding stock.

(20) *Peroxyacetic/peracetic acid (CAS #—79–21–0)*—for sanitizing facility and processing equipment.

(21) *Phosphoric acid*—allowed as an equipment cleaner, Provided, That, no direct contact with organically managed livestock or land occurs.

(22) *Poloxalene (CAS #—9003–11–6)*—in accordance with approved labeling.

(23) *Tolazoline (CAS #—59–98–3)*—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 Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.

(24) *Xylazine (CAS #—7361–61–7)*—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 Animal Medicinal Drug Use Clarification Act of 1994 and 21 CFR part 530 of the Food and Drug Administration regulations.

(b) As topical treatment, external parasiticide or local anesthetic as applicable.

(1) Copper sulfate.

(2) Iodine.

(3) *Lidocaine*—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(4) *Lime, hydrated*—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(5) *Mineral oil*—for topical use and as a lubricant.

(6) *Procaine*—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.

(c) *As feed supplements*—Milk replacers without antibiotics, as emergency use only, no nonmilk products or products from BST treated animals.

(d) As feed additives.

(1) *Calcium propionate (CAS #—4075–81–4)*—for use only as a mold inhibitor in dry herbal products.

(2) *DL*—Methionine, DL-Methionine—hydroxy analog, and DL-Methionine—hydroxy analog calcium—for use only in organic poultry production until October 1, 2008.

(3) Trace minerals, used for enrichment or fortification when FDA approved.

(4) Vitamins, used for enrichment or fortification when FDA approved.

(e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or a synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) *EPA List 4*—Inerts of Minimal Concern.

(2) [Reserved]

(f) Excipients, 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 a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

* * * * *

Dated: July 3, 2006.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

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