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[Docket Number AMS–TM–07–0123; TM–03–04]

RIN 0581–AC62

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

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List) regulations to enact 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 final rule adds two defined terms and nine substances, along with any restrictive annotations, and a category of substances to the National List.

DATES: *Effective Dates:* This final rule becomes effective December 13, 2007.

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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. This National List identifies the synthetic substances that may be used and the nonsynthetic (natural) substances that may not be used in organic production. The National List also identifies synthetic, nonsynthetic nonagricultural and nonorganic agricultural substances that may be used in organic handling. The Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. 6501 *et seq.*), and NOP regulations, in § 205.105, specifically prohibit the use of any synthetic substance for organic production and handling unless the synthetic substance is on the National List. Section 205.105 also requires that any nonorganic agricultural, nonsynthetic nonagricultural substance used in organic handling must also be on the National List.

Under the authority of the OFPA, the National List can be amended by the Secretary based on substance recommendations developed by the NOSB. This final rule amends the National List to enact recommendations submitted to the Secretary by the NOSB from November 15, 2000, through March 3, 2005.

II. Overview of Amendments

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

Section 205.2 Terms Defined

This final rule amends § 205.2 of the NOP regulations by adding the following terms:

AMDUCA. The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103–396).

Excipients. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

Section 205.603 Synthetic Substances Allowed for Use in Organic Livestock Production

This final rule amends paragraph (a) of § 205.603 of the National List regulations by adding the following substances:

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, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (1) Use by or on the lawful written order of a licensed veterinarian, in full compliance with the AMDUCA; and (2) a meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

Butorphanol (CAS #–42408–82–2)—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. Also, for use under 7 CFR part 205, the NOP requires: (1) Use by or on the lawful written order of a licensed veterinarian, in full compliance with the AMDUCA; and (2) a meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

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. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian, in full compliance with the AMDUCA.

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

Poloxalene (CAS #–9003–11–6)—for use under 7 CFR part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

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. Also, for use under 7 CFR part 205, the NOP requires: (1) Use by or on the lawful written order of a licensed veterinarian, in full compliance with the AMDUCA; (2) use only to reverse the effects of sedation and analgesia caused by Xylazine; and (3) a meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

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. Also, for use under 7 CFR part 205, the NOP requires: (1) Use by or on the lawful written order of a licensed veterinarian, in full compliance with the AMDUCA; (2) the existence of an emergency; and (3) a meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

This final rule amends § 205.603 of the National List regulations by adding a new paragraph (f) to read as follows:

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.

This final rule also makes a technical correction to § 205.603 paragraph (e) by removing the word ''a'' from between ''or'' and ''synthetic''.

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 final 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). The proposed rule for this final rule was published on July 17, 2006 (71 FR 40624).

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 substance recommendations developed by the NOSB. Sections 6518(k)(2) and 6518(n) of OFPA authorize the NOSB to develop substance recommendations 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 (72 FR 2167) 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 final rule is not intended to have a retroactive effect.

States and local jurisdictions are preempted under the OFPA 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 § 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under §§ 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 § 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 § 2120(f) of the OFPA (7 U.S.C. 6519(f)), this final 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 final rule would not be significant. The effect of this final rule would be to allow the use of additional substances in agricultural production and handling. This action would modify the regulations to 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 final 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. 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 2006, the number of certified organic crop, livestock, and handling operations totaled over 14,800 operations based on reports by certifying agents to the NOP as part of their annual reporting requirements. AMS believes that most of these entities would be considered small entities under the criteria established by SBA.

U.S. sales of organic food and beverages have grown from $1 billion in 1990 to nearly $17 billion in 2006. Organic food sales are projected to reach $23.8 billion for 2010. The organic industry is viewed as the fastest growing sector of agriculture, currently representing nearly 3 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 including a 22 percent increase in 2006.

In addition, 95 certifying agents are currently accredited by USDA to provide certification services to producers and handlers under the NOP. A complete list of names and addresses of accredited certifying agents may be found on the 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 final 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. Received Comments on Proposed Rule TM–03–04

AMS received 79 comments on proposed rule TM–03–04. Comments were received from organic livestock producers, veterinarians, accredited certifying agents, consumers, retailers, trade associations, manufacturers of animal medications, and public interest groups. A number of comments expressed total opposition to all amendments proposed in TM–03–04 and asserted that such amendments weakened the NOP regulations. A few comments supported the addition of all the proposed amendments without changes. Many comments indicated conditional support for some of the proposed amendments; however, they suggested modifications be made to their inclusion on the National List. Such comments conveyed that the proposed amendments altered the original intent for how the NOSB recommended the substance be used in organic livestock production. Some of those comments proposed that if the substance was not to be listed as recommended by the NOSB, then the proposed amendment should not be added to the National List.

Additional comments raised concern regarding USDA's decision not to include certain substances on the National List. These substances include activated charcoal, calcium borogluconate, calcium propionate, kaolin pectin, mineral oil, propylene glycol, and epinephrine. Comments also indicated that a few of the proposed amendments required further clarification or correction to avoid misinterpretation of the regulations and misapplication of the substance.

Changes Made Based On Comments

The following changes are made based upon comments received.

Calcium propionate as a mold inhibitor in dry formulated herbal products. Some comments expressed opposition to the proposed amendment to add Calcium propionate as a mold inhibitor in dry herbal products to § 205.603(d). At their May 2003 meeting, the NOSB recommended adding Calcium propionate as a mold inhibitor in dry formulated herbal ''remedies.'' Comments on Calcium propionate concluded that the NOSB did not recommend Calcium propionate to be added onto the National List as a livestock feed additive under § 205.603(d); rather, these comments argued that the NOSB recommended Calcium propionate be included as a ''medical treatment'' and listed under § 205.603(a). Comments further suggested that if calcium propionate could not be listed under § 205.603(a) that it should not be included on the National List because the authorization for the substance could be misinterpreted to allow its use for organic livestock feed, which was not the intent of the proposal or the NOSB recommendation.

We agree with these comments that the proposed amendment for Calcium propionate did not correspond with the NOSB recommendation. Based on the consultation between USDA and FDA, we were informed that ''dry formulated herbal remedies'' are not recognized as a ''medical treatment'' for animal illness and could not be authorized as such in the **Federal Register** and under § 205.603(a) of the National List without having been approved by FDA through a New Animal Drug Application (NADA).

As a result, USDA researched the most appropriate way to include the substance on the National List to reflect the NOSB's recommendation. To that effect, we recognized that Calcium propionate did not have any approved uses as a medical treatment under the FDA regulations. However, under 21 CFR 582.3221 (Animal Drugs, Feeds, and Related Products), it is approved as a chemical preservative that is Generally Recognized as Safe. Therefore, since ''dry formulated herbal remedies'' are not recognized as medical treatments under the FDA's regulations and could not be prescribed as such in the National List, the USDA believed that it could implement the recommendation

and intent of the NOSB by permitting the use of Calcium propionate as a mold inhibitor in dry formulated ''products'' (instead of ''remedies'') by authorizing it as a feed. We concluded that herbs (agricultural products) would be fed to an animal and would therefore be considered part of the feed provisions of the National List.

In addition to the general public comments received on Calcium propionate, we received comments from the FDA concerning the proposed language to authorize the use of Calcium propionate as a ''mold inhibitor.'' The FDA shared that Calcium propionate is not authorized for use as a ''mold inhibitor,'' but a ''chemical preservative.'' Therefore, it must only be recognized for use within the parameters for which it has been authorized. The FDA also commented that the AMDUCA does not apply to Calcium propionate and cannot be used to attempt broader uses than authorized by the FDA.

As a result, based on comments received on Calcium propionate's proposed addition to § 205.603(d) of the National List and information shared by the FDA, we have decided not to add Calcium propionate to the National List. Instead, we are referring this substance back to the NOSB for the purpose of reconsidering its placement on the National List (*i.e.* § 205.603(d)), as it relates to the regulatory provisions of the FDA).

Incorrect CAS number for Butorphanol. One commenter observed that the proposed rule included an incorrect CAS number for Butorphanol. The proposed rule listed Butorphanol's CAS number as 14887–18–9. This comment indicated that the proper CAS number is 42408–82–2. NOP research confirmed the CAS number provided within the comment is accurate. Therefore, we agree with this comment and have inserted the proper CAS number into the final rule.

Extended Withdrawal Periods. Many commenters disagreed with USDA's decision to omit the NOSB's recommendations to extend the withdrawal periods for a number of proposed livestock medications (*e.g.* Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine). Commenters argued that the NOP has the authority to require stricter standards for animal drug use than those specified by the FDA. According to the commenters, all drugs permitted for use in organic farming are subject to stricter standards than those used by nonorganic farmers, because they are subject to certifiers' review and approval in an Organic System Plan (OSP). Commenters also noted that there are currently several livestock medications (Ivermectin, Lidocaine, and Procaine) on the National List whose withdrawal periods already extend beyond that required by FDA.

Commenters expressed that USDA should either accept the NOSB's recommendation to extend the withdrawal period of the proposed livestock medications or not amend the National List at all. Without the extended withdrawal period, according to these commenters, the NOSB's recommendations would be weakened and the synthetic substances would be allowed to be used in ways that the NOSB did not intend.

As a proposed compromise to satisfy the intent of the NOSB, many commenters suggested that USDA should consider amending the annotations of Atropine, Butorphanol, Flunixin, Furosemide, Tolazoline, and Xylazine by establishing extended withdrawal periods, calculated using withdrawal times from the Food Animal Residue Avoidance Databank (FARAD). The FARAD is a National Food Safety Project administered through the USDA Cooperative State Research, Education, and Extension Service. It is a system designed to provide livestock producers, extension specialists, and veterinarians with practical information on how to avoid drug, pesticide and environmental contaminant residue problems. FARAD is a repository of comprehensive residue avoidance information. It is also sanctioned to provide ''withholding period'' (also known as withdrawal period) estimates to the U.S. Pharmacopeia-Drug Information (USP–DI) Veterinary Medicine Advisory Committee. Commenters suggested that USDA account for an extra margin of at least double the withdrawal times of FARAD to safely capture the intent of the NOSB.

USDA agrees with the position stated in the comments. Since many of the aforementioned livestock medications are being authorized for use under AMDUCA and do not have formal FDA approved labels for the use recommended by the NOSB, veterinarians who are authorized to administer the medical treatment to organic livestock would be responsible for establishing a substantially extended withdrawal period prior to the marketing of milk, meat, eggs, or other edible products. The FDA requires that these withdrawal periods be supported by appropriate scientific information, if applicable. The FDA also requires that the veterinarian take appropriate measures to assure the assigned timeframes for withdrawal are met and that no illegal drug residues occur in any food-producing animal subjected to extra-label treatment (21 CFR 530.20(a)(2)(ii); (iv)). Therefore, in an effort to ensure uniformity and consistency regarding the application of withdrawal periods, USDA has amended the annotations of Atropine, Butorphanol, Tolazine, and Xylazine to reflect minimum withdrawal periods that are double the FARAD withdrawal period suggested for the administration of the referenced livestock medication.

With respect to the withdrawal periods for Flunixin and Furosemide, however, these drugs *do* have FDA approved labels for the use recommended by the NOSB and *were not* proposed for use in organic livestock production under AMDUCA but rather existing FDA approved animal drug use and labeling, 21 CFR part 520. As a result, the withdrawal period associated with the use of these substances under the NOP would be based upon the withdrawal period established by the FDA, as opposed to a FARAD withdrawal period.

Based on public comment, USDA consulted further with the FDA, concerning the ability to extend the withdrawal period on these approved drugs. Based on our consultations, USDA agreed to clarify the rationale for extending the FDA established withdrawal period. Secondly, USDA agreed to clarify the language used to authorize the use of the substances by indicating the extended withdrawal periods (at least two-times that required by the FDA) were only relevant for use of the substances under the NOP regulations.

Therefore, to clarify our rationale for extending the withdrawal periods established by the FDA, we acknowledge that this determination was not based on scientific research or risk assessments. The decision to extend the FDA withdrawal periods (or any other withdrawal period) for the use of Flunixin and Furosemide (and other substances) was based on consumer preference and the recommendations of the NOSB. FDA exercises full responsibility for determining and enforcing the withdrawal intervals for animal drugs. No food safety arguments are used or implied to support the use of extended withdrawal periods authorized under the NOP regulations. Rather, we determined that extended withdrawal periods are more compatible with consumer expectations of organically raised animals.

Verification of lawful order of a licensed veterinarian. Federal law restricts Atropine, Butorphanol, Magnesium hydroxide, Tolazine, and

Xylazine to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. For use under 7 CFR part 205, the NOP is requiring use by or on the lawful written order of a licensed veterinarian. Further, under the NOP, a written order is necessary for the livestock producer to prove compliance with paragraph (b) of § 205.238 Livestock health care practice standard. Written orders will also facilitate compliance with the recordkeeping provisions of § 205.103.

Other use restrictions for Tolazine and Xylazine. In addition to the use restrictions noted above, in response to comments, the NOP has added the following use restrictions. For Tolazine, the NOP has added the requirement that Tolazine only be used to reverse the effects of sedation and analgesia caused by Xylazine as originally recommended by the NOSB at its September 17–19, 2002, meeting in Washington, DC. For Xylazine, the NOP has added the requirement for the existence of an emergency as originally recommended by the NOSB at its September 17–19, 2002, meeting in Washington, DC.

Excipients. Commenters suggested that the proposed amendment to include excipients onto the National List was too broad or needed further clarification to reduce possible confusion for producers, certifying agents, and consumers. Commenters asserted that the proposed language could lead readers to believe that excipients are permitted for use in livestock feed or feed supplements.

We do not agree that the proposed language is so misleading to readers. However, we do believe that a definition of excipients would help clarify its meaning. Therefore, we have amended the regulations to include the following definition for excipients: ''any ingredients intentionally added to livestock medications but that do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.''

Poloxalene annotation. A number of comments objected to USDA omitting the NOSB's recommendation to authorize the use of Poloxalene with the annotation ''only be used for emergency treatment of bloat.'' With regard to Poloxalene and the proposed language in TM–03–04, commenters expressed concern that the proposed language would allow routine use of Poloxalene. As a result, commenters believed the proposed language for Poloxalene represents the use of a substance that was not approved by the NOSB.

We agree that the proposed language in TM–03–04, authorizing the use of Poloxalene, did not restrict its use for only the ''emergency treatment of bloat,'' as the NOSB had recommended. Based on our initial consultations with the FDA, we originally proposed the use of the substance as follows ''in accordance with approved labeling.'' However, after reviewing the comments and further consultation with the FDA, we have modified the authorizing language to (1) reflect the intent of the NOSB and (2) clarify the language used to authorize the use of the substance by indicating that the restricted use of Poloxalene (only for the emergency treatment of bloat) is only relevant for use of the substance under the NOP.

Exclusion of Moxidectin. A number of commenters requested that USDA include Moxidectin on the National List, as the NOSB had recommended (to control internal parasites). We did not propose to add Moxidectin to the National List because the substance is a macrolide antibiotic and does not comply with the April 22, 2005, NOP policy statement on antibiotic use in livestock production. The statement provides that the use of antibiotics and other prohibited substances is not allowed for organically produced livestock or their edible products once a producer is certified organic. Commenters stated that USDA's rationale for not adding Moxidectin to the National List was arbitrary and without scientific or regulatory basis. Commenters argued that Moxidectin should not be considered an antibiotic, but a parasiticide, and therefore should be allowed for use as medication to treat organic livestock. One commenter presented information that attempted to delineate the difference between an antibiotic and a parasiticide. The comment argued that the defining feature of an antibiotic is its ability to inhibit the growth of microorganisms or kill them outright. It included that Moxidectin does not have this capacity. Instead, Moxidectin targets parasites, rather than bacterial infections.

We have verified the information shared through public comment and agree that Moxidectin, even though an animal drug that is a macrolide antibiotic, does not function as an antibiotic (targeting bacterial infections), but as a parasiticide (targeting parasites/helminthes, e.g., roundworms, lungworms, hookworms, flatworms, etc.). As a result, we will initiate proposed rulemaking to authorize Moxidectin as a livestock medication to control internal parasites.

Removal of Bismuth subsalicylate (CAS #–14887–18–9). Bismuth subsalicylate was proposed for inclusion on the National List. It was proposed for use as a drug restricted 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 FDA regulations. In the proposed rule, the NOP shared that consultations with the FDA revealed that Bismuth subsalicylate is approved as a drug for use in humans (FDA, ''Approved Drug Products with Therapeutic Equivalence Evaluations, 2005'') and that New Animal Drug Application (NADA) approvals for Bismuth subsalicylate were not identified. The NOP further stated that despite the absence of a NADA approval for Bismuth subsalicylate, the substance 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.'' This action was based on the rationale that Bismuth subsalicylate was an approved human drug and qualified for use under the provisions of AMDUCA.

However, in response to the proposed rule, the FDA informed the NOP that Bismuth subsalicylate *could not* be authorized for use in livestock production under the AMDUCA and 21 CFR part 530 of the FDA regulations, because Bismuth subsalicylate is not approved as an independent, active ingredient for use as a human drug, but only in combination with Metronidazole and Tetracycline hydrochloride. The FDA further commented that over-the-counter medications do not qualify for use under the provisions of AMDUCA and 21 CFR part 530. As a result, they advised the NOP to remove Bismuth subsalicylate from the proposed amendments to the National List; Bismuth subsalicylate has been removed from inclusion.

Other Changes Made

Several of the new substance listings contain the term ''AMDUCA.'' For the convenience of persons using the NOP regulations we have added a definition of AMDUCA to § 205.2. That definition reads: ''AMDUCA. The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103–396).''

While preparing this final rule, we noted a technical error in the wording of § 205.603(e). Accordingly, this final

rule also makes a technical correction to § 205.603 paragraph (e) by removing the word ''a'' from between ''or'' and ''synthetic''. Section 205.603(e) now reads: ''As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.''

Changes Requested But Not Made

A number of commenters opposed the addition of *any* of the proposed amendments to the National List. The majority of these comments did not provide any evidence under the OFPA and NOP regulations that would support the position stated. Instead, these commenters stated the addition of any of the proposed amendments weakened the NOP regulations and compromised the integrity of organic foods. We considered these comments but have determined that the record supports the need for livestock medications in the interest of humane treatment of livestock. We believe commenters' concerns have been addressed by including double withdrawal periods and other use restrictions.

Six non-accepted substances. Several comments, including a number from organic dairy farmers, supported adding Activated charcoal, Calcium borogluconate, Calcium propionate (as a medical treatment for milk fever), Kaolin pectin, Mineral oil, and Propylene glycol onto § 205.603(a) as substances that should be allowed for use as medical treatments in organic livestock production. These substances were not included as amendments to the National List in the proposed rule. The NOSB recommended that the Secretary include these substances onto the National List, in § 205.603, as veterinary treatments in organic livestock production. Comments in support of including these substances onto the National List argued that these substances were essential tools for dairy farmers, effective in restoring animal health, and widely available and commonly used by livestock producers and veterinarians, with no significant environmental impacts. Additionally, a few of these commenters argued that FDA considers these drugs to be a low regulatory priority or ''allowed by regulatory discretion.''

As stated in the proposed rule, consultation with the FDA revealed that Activated charcoal, Calcium borogluconate, Calcium propionate, Kaolin pectin, Mineral oil, and Propylene glycol have *not* received approval through the FDA drug approval process to be authorized as medical treatments for livestock. Consultation also revealed that the proposed substances could not qualify for extra-label use by a licensed veterinarian under AMDUCA. As a result, the synthetic forms of these substances remain prohibited for use in organic livestock production.

One commenter asserted that USDA should have not stated that the six substances could not be used in organic livestock production, because some of the substances could be sourced and used in nonsynthetic form. USDA agrees that nonsynthetic forms of the medication would not be prohibited from use in organic livestock production. The proposed rule did not address the nonsynthetic forms of the medications because the NOSB's recommendations only addressed the synthetic forms. As a result, we reiterate that the prohibited use of the six substances was made in the context of the synthetic form of the substances, not the nonsynthetic form.

Epinephrine as a prohibited nonsynthetic substance. A few comments were received concerning USDA's decision not to include Epinephrine as a prohibited nonsynthetic substance on the National List. Some comments were in favor of the proposed action on Epinephrine, while a few did not favor USDA's decision to exclude the substance from the National List. We also received one comment that recommended USDA, with respect to the FDA restriction on the use of Epinephrine, consult with the NOSB to see if there is still a need to identify the substance as a prohibited nonsynthetic on the National List.

The proposed rule acknowledged that Epinephrine is a nonsynthetic substance; and it emphasized that nonsynthetic substances are allowed in organic production, unless prohibited. For instance, under the NOP regulations, a livestock producer may not administer animal drugs in violation of the Federal Food, Drug and Cosmetic Act. The proposed rule also noted that the FDA regulations currently restrict the use of the medication to the emergency treatment of anaphylactic shock in cattle, horses, sheep, and swine, which is what the NOSB had recommended. As a result, we did not see a clear need to include the substance on the National List. USDA will consult with the NOSB to see if there is still a need to identify Epinephrine as a prohibited nonsynthetic on the National List.

F. Effective Date.

This final rule reflects recommendations submitted to the Secretary by the NOSB. The substances being added to the National List were based on petitions from the industry and evaluated by the NOSB using criteria in the Act and the regulations. Because these substances are crucial to organic livestock production operations, producers should be able to use them in their operations as soon as possible. Accordingly, AMS finds that good cause exists under 5 U.S.C. 553(d)(3) for not postponing the effective date of this rule until 30 days after publication in the **Federal Register**.

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 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 205.2 is amended by adding two new terms in alphabetical order to read as follows:

§ 205.2 Terms defined.

* * * * *

AMDUCA. The Animal Medicinal Drug Use Clarification Act of 1994 (Pub. L. 103–396).

* * * * *

Excipients. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g., enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, diluents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

* * * * *

■ 3. 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.

(i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.

(ii) 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, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.

(4) Biologics—Vaccines.

(5) Butorphanol (CAS #–42408–82–2)—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. Also, for use under 7 CFR Part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian; and

(ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.

(6) 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.

(7) 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.

(i) Calcium hypochlorite.

(ii) Chlorine dioxide.

(iii) Sodium hypochlorite.

(8) Electrolytes—without antibiotics.

(9) Flunixin (CAS #–38677–85–9)—in accordance with approved labeling; except that for use under 7 CFR Part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.

(10) Furosemide (CAS #–54–31–9)—in accordance with approved labeling; except that for use under 7 CFR Part 205, the NOP requires a withdrawal period of at least two-times that required that required by the FDA.

(11) Glucose.

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

(13) Hydrogen peroxide.

(14) Iodine.

(15) 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. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.

(16) Magnesium sulfate.

(17) Oxytocin—use in postparturition therapeutic applications.

(18) 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.

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

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

(21) Poloxalene (CAS #–9003–11–6)—for use under 7 CFR Part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.

(22) 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. Also, for use under 7 CFR Part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(23) 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. Also, for use under 7 CFR Part 205, the NOP requires:

(i) Use by or on the lawful written order of a licensed veterinarian;

(ii) The existence of an emergency; and

(iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.

(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.

(7) Sucrose octanoate esters (CAS #s–42922–74–7; 58064–47–4)—in accordance with approved labeling.

(c) As feed supplements—None.

(d) As feed additives.

(1) DL–Methionine, DL–Methionine—hydroxy analog, and DL–Methionine—hydroxy analog calcium (CAS #–59–51–8; 63–68–3; 348–67–4)—for use only in organic poultry production until October 1, 2008.

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

(3) 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 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: December 5, 2007.

Lloyd C. Day,

Administrator, Agricultural Marketing Service.

[FR Doc. E7–23915 Filed 12–11–07; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL RESERVE SYSTEM

12 CFR Part 220

[Regulation T; Docket No. R–1301]

Credit by Brokers and Dealers

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; correcting amendment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is amending Regulation T (Credit by Brokers and Dealers) to correct a cross-reference in one of its interpretations.

DATES: *Effective Date:* December 12, 2007.

FOR FURTHER INFORMATION CONTACT: Scott Holz, Senior Counsel, Legal Division (202–452–2966). For users of the Telecommunications Device (TDD) only, please call 202–263–4869.

SUPPLEMENTARY INFORMATION: The National Securities Markets Improvement Act of 1996 (NSMIA). (Pub. L. 104–290, 110 Stat. 3416) amended section 7 of the Securities Exchange of 1934 (15 U.S.C. 78g) to limit the Board's authority to impose restrictions on credit extended, maintained, or arranged to or for a member of a national securities exchange or a registered broker or dealer, a substantial portion of whose business consists of transactions with persons other than brokers or dealers, or to finance its activities as a market maker or an underwriter. Restrictions on these types of credit were found at that time in Regulations G, T and U (12 CFR Parts 207, 220, and 221, respectively).

NSMIA gave the Board the authority to maintain or adopt restrictions on these types of credit if it determines that such action is necessary or appropriate in the public interest or for the protection of investors. In November 1996, the Board adopted an interpretation of its margin regulations (1996 interpretation), indicating that the Board had not made such a finding (61 FR 60166, November 26, 1996). The 1996 interpretation stated the Board's belief that the restrictions on these types of credit found in the Regulations G, T and U had been superseded by NSMIA.

NSMIA also repealed section 8(a) of the Securities Exchange Act of 1934, dealing with extensions of credit to brokers and dealers collateralized with exchange-traded securities. The Board's 1996 interpretation indicated that the provisions in Regulations G, T and U adopted to implement section 8(a) of the Securities Exchange Act of 1934 were without effect in light of NSMIA.

The text of the 1996 interpretation was published as part of Regulation G, and Regulations T and U were amended with interpretations that referred to the text of the 1996 interpretation appearing in Regulation G.

In 1998, the Board adopted regulatory amendments to remove the restrictions that conflicted with NSMIA (63 FR 2806, January 16, 1998). As part of this process, the Board amended the 1996 interpretation to delete references to the conflict between the regulations and NSMIA. The remaining provisions of Regulation G, including the amended 1996 interpretation, were incorporated into Regulation U. However, the reference in Regulation T to the text of the 1996 interpretation was inadvertently not changed to reflect the elimination of Regulation G. Today's action will correct this cross-reference by amending Regulation T to reflect the fact that the text of the amended 1996 interpretation now appears in Regulation U.

List of Subjects in 12 CFR Part 220

Banks, banking, Brokers, Credit, Federal Reserve System, Margin, Margin requirements, Reporting and recordkeeping requirements, Securities.

■ For the reasons set forth in the preamble, part 220 is amended to read as follows:

PART 220—CREDIT BY BROKERS AND DEALERS (REGULATION T)

■ 1. The authority citation for part 220 continues to read as follows:

Authority: 15 U.S.C. 78c, 78g, 78q, and 78w.

§ 220.132 [Amended]

■ 2. In § 220.132, introductory paragraph, replace the phrase ''§ 207.114'' with ''§ 221.125.''

By order of the Secretary of the Board, acting pursuant to delegated authority for the Board of Governors of the Federal Reserve System, December 7, 2007.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. E7–24052 Filed 12–11–07; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 26, 121, and 129

[Docket No. FAA–2005–21693; Amendment Nos. 26–1, 121–337, 129–44]

RIN 2120–AI32

Damage Tolerance Data for Repairs and Alterations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This final rule requires holders of design approvals to make available to operators damage tolerance data for repairs and alterations to fatigue critical airplane structure. This rule will support operator compliance with the Aging Airplane Safety final rule with respect to the requirement to incorporate into the maintenance program, a means for addressing the adverse effects repairs and alterations may have on fatigue critical structure. The intent of this final rule is to ensure the continued airworthiness of fatigue critical airplane structure by requiring design approval holders to support operator compliance with specified damage tolerance requirements.

DATES: These amendments become effective January 11, 2008.

FOR FURTHER INFORMATION CONTACT: If you have technical questions about this action, contact Greg Schneider, ANM–115, Airframe and Cabin Safety, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, Washington 98057–3356, telephone: (425–227–2116); facsimile (425–227–1232); e-mail *greg.schneider@faa.gov.* Direct any legal questions to Doug Anderson, ANM–7, Office of Regional Counsel, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98057–3356; telephone (425) 227–2166; facsimile (425) 227–1007; e-mail *Douglas.Anderson@faa.gov.*

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the