

Item A—Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List:

Petition to add

INJECTABLE VITAMIN AND MINERAL FORMULATIONS WITH ASSOCIATED EXCIPIENTS AS NUTRITIVE SUPPLEMENTS IN ACCORDANCE WITH FDA

to the National List as

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

Item B—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned:

1. The substance's chemical or material common name.

Injectable vitamin and mineral formulations

2. The manufacturer's or producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.

Petitioner: Hubert J. Karreman, VMD
555 Red Hill Road
Narvon, PA 17555
717-768-7088

There are more than two dozen pharmaceutical companies which manufacture injectable vitamin and mineral formulations. They are not involved with this petition since individual formulations are not being specifically petitioned for use in organic livestock but rather the category to allow injectable vitamin and mineral formulations in general.

3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (e.g., cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (e.g., ingredient, flavoring agent, emulsifier, processing aid).

Propose new section heading in 205.603:

Injectable vitamin and mineral formulations with associated excipients as nutritive supplements in accordance with FDA

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.

Activity for which the substance will be used:

Injectable Vitamins: For use as a nutritive supplement

Injectable Minerals: For use as a nutritive supplement

Substances' rate and method of application:

Injectable vitamins, per label directions or on the order of a licensed veterinarian.

Injectable minerals, per label directions or on the order of a licensed veterinarian.

- 5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.**

Many patents for the manufacture of vitamin and mineral formulations are in the public domain

- 6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.**

Injectable vitamins and minerals are technically not allowed since there is no specific listing or category for them in 7CFR205.603, therefore this information is not readily available. However, informal information shows that injectable vitamins and minerals for supplementation have been widely used by certified organic livestock farmers since the Rule's implementation in October 2002.

- 7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.**

The FDA Center for Veterinary Medicine oversees injectable vitamin and mineral use. Injectable formulations either have the federal prescriptive legend "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." or have adequate labeling for lay use. Most of the vitamin and mineral formulations also have a National Drug Catalogue (NDC) number. It is proposed that injectable vitamin and mineral formulations be allowed for organic livestock when in accordance with FDA CVM.

- 8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.**

There are various CAS numbers associated with vitamins and minerals and are in the public domain.

- 9. The substance's physical properties and chemical mode of action including:**
- (a) Chemical interactions with other substances, especially substances used in organic production;**
 - (b) toxicity and environmental persistence;**
 - (c) environmental impacts from its use and/ or manufacture;**
 - (d) effects on human health; and,**
 - (e) effects on soil organisms, crops, or livestock.**

Injectable vitamins and minerals used in livestock are generally given only one time or at very infrequent intervals. The intent is to be a supplement. Supplements given by injection are not something farmers want to do routinely, thus will be done sparingly and only when necessary. (a) They are not mixed with other typical livestock inputs. (b) when used according to label direction or use by or on the order of a licensed veterinarian, toxicity isn't an issue. (c) vitamin and mineral formulations have been manufactured for decades without much modification and their manufacturing processes are in the public domain. (d) the injectable vitamin and mineral formulations, while the petitioned category is for livestock, have parallel products made for human use (e) effects on livestock would be to correct perceived deficiencies and therefore likely not cause any environmental impact any more than normal vitamin and mineral metabolism might cause.

- 10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a**

substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

MSDS sheets for the various vitamins and minerals are in the public domain.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

It would be interesting to know of contrasting positions to injectable vitamin and mineral formulations that benefit the health and welfare of animals.

12. A "Petition Justification Statement" which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

- **Explain why the synthetic substance is necessary for the production or handling of an organic product.**

Injectable vitamin and mineral formulations as supplements for animals needing restoration of normal levels of vitamins and minerals is essential to livestock health and welfare.

- **Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.**

While vitamins and minerals are allowed as feed additives (205.603(d)) and may perhaps exist as non-synthetic as feed additives, injectable formulations are synthetically produced, both the active materials and their excipients. An in-depth search was done to discover if any injectable vitamins and minerals are wholly non-synthetic and none were found. Non-synthetic vitamin and mineral feed additives are fine if the animal is eating but lack effect if the animal has reduced feed intake or the feed is refused due to poor quality. Proper nutrition should be in place (as reflected in the Organic System Plan) but there are individual animals that may become depleted in certain vitamins and minerals during the course of their life. Administration of parenteral vitamins and minerals via injection may be necessary to systemically elevate such vitamins and minerals in a rapid manner.

- **Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.**

Enhanced livestock health and welfare.

13. A Confidential Business Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners

should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Final determination regarding whether to afford CBI treatment to submitted petitions will be made by USDA pursuant to 7 CFR 1.27(d). Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

No CBI is being sought



United States
Department of
Agriculture

Agricultural
Marketing
Service

STOP 0268 – Room 4008-S
1400 Independence Avenue, SW.
Washington, D.C. 20250-0200

March 3, 2009

Hubert Karreman, VMD
555 Red Hill Road
Narvon, Pennsylvania 17555

Dear Dr. Karreman,

Thank you for your petition of February 17, 2009, which requests the addition of Injectable Vitamins and Minerals onto section 205.603 of the National Organic Program's (NOP) National List of Allowed and Prohibited Substances (National List).

We have reviewed your petition and determined that the Injectable Vitamins and Minerals petition cannot move forward through the petition process for the following reason:

1. Incomplete petition information provided within the Injectable Vitamins and Minerals petition. As submitted, there is insufficient information within your petition to conduct an adequate petition review to add Injectable Vitamins and Minerals to the National List.

To assist you in the development of your petition, we recommend that you modify your current petition to address these items:

- Provide comprehensive information that adequately addresses each item in the attached document, "National Organic Program – Submission of Petitions of Substances for Inclusion on or Removal from the National List of Substances Allowed and Prohibited in Organic Production and Handling." Please provide concise comprehensive responses to information items 2, 4, 5, 6, 8, 10 and 11.

Should you have any further questions, please contact me by phone at (202) 702-3252 or by e-mail at bob.pooler@usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Robert L. Pooler".

Robert L. Pooler
Standards Development and Review Branch
USDA National Organic Program

cc: NOSB

Attachment