ORTHOPAEDIC RESEARCH CENTER
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April 12, 2021

To Whom It May Concern,

This is a short note to introduce Grand Meadows.

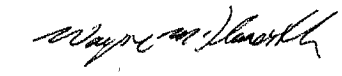
While myself and my team at Colorado State University still feels that the definitive research establishing clinical efficacy of oral glycosaminoglycans is lacking, there is clearly a substantial demand for these types of products.

This demand has been satisfied with a bewildering array of products, now numbering over 350 in the US market alone. As this marketplace has been, until recently, largely unregulated, it has fostered an environment where many products are manufactured under dubious standards and often misrepresented to consumers.

Grand Meadows and its company President, Nick Hartog, have been leading industry participants in bringing levels of accountability and manufacturing standards to an industry that was woefully in need of an improved image. Nick was one of the founding members and sits on the Board of the NASC (National Animal Supplement Council www.nasc.cc) and has been instrumental in establishing many of the initiatives that have earned the NASC the respect and cooperation of the FDA-CVM (Center for Veterinary Medicine). In the 20 years that the NASC has been in place they have introduced a series of strict requirements for member companies to incorporate into their operations. Every member company is subjected to a bi-annual audit to ensure compliance and they need to pass that audit in order to be able to display the NASC Seal on their packaging and marketing materials. While there are a great number of different requirements to pass the audit some of the more important elements are as follows: Monthly adverse event reporting, labels that follow a strict template depending on the intended use of the product, random testing of member products to see if they match label claim and strict enforcement procedures in the event they fail. Raw material testing and finished product testing to name a few. The NASC has truly had a profound impact on the safety, transparency and legitimacy of the animal health supplement industry.

While I emphatically do not endorse any of the Grand Meadows products I do believe that this company represents the best example of how to be a responsible industry participant.

Sincerely,



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University Distinguished Professor in Orthopaedics,
Barbara Cox Anthony University Chair in Orthopaedic Research
Founding Director of Orthopaedic Research Center Emeritus

Department of Health and Human Services
Food and Drug Administration

REPORT OF INSPECTION FOR COMPLIANCE WITH 21 CFR §589.2000 and §589.2001

FEI NUMBER:

Firm (Legal) Name: GRAND MEADOWS INC	Date Current Inspection Ended: 9-30-2010
Firm (Physical) Address: 1607-E WEST ORANGEGROVE	Lead Investigator: MICHAEL DAVIDSON
Firm City: ORANGE CA 92868-1114	Lead Affiliation (Check one): ☐ Federal ☒ State Agency (Enter name below) CA DEPT OF FOOD + AGRICULTURE
Firm State: CA / ZIP Code: 92868 / Telephone Number: 714-628-1690	
Name and title of person(s) interviewed: COLLEEN GEOFFROY, GENERAL MANAGER	GPS Coordinates of Inspected Site:
	FDA District Office: LOS-DO
	Name and title of most responsible person at this site: NICK HARTOG - PRESIDENT

☐ Information above includes changes to firm's name and/or address

Operational Status *(Check only one)* *(See Instructions)* **[If firm is OOB, Skip ALL Sections!]**
☒ Operational ☐ Seasonal ☐ Inactive ☐ Out of Business

Section 1 — Complete for ALL firms

1. a) Type of firm inspected? ***(Check ALL that apply)***

☐ Renderer ☐ Distributor/Retailer ☐ Pet Food Manufacturer ☐ Feeder of Ruminants
☐ Protein Blender ☐ Feed Mill (FDA Licensed) ☐ Animal Feed/Pet Food Salvager ☐ Human Food Processor
☐ Transporter (Hauler) ☐ Feed Mill (not FDA Licensed) ☐ On-farm Feed Mixer
☒ Other *(Specify)*: PACKAGING VITAMIN, MINERAL PREMIXES FOR EQUINES AND DOGS

b) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of ***ruminant*** animals?
☐ Yes ☒ No

c) Does the firm handle (manufacture, process, blend, distribute, transport or use) feed or feed ingredients that are intended for the feeding of ***non-ruminant*** animals?
☒ Yes ☐ No

d) Is the firm aware of the BSE rule, 21 CFR §589.2000? ☐ Yes ☐ No

2. If the firm is manufacturing feed, does it use tallow (animal fat from cattle) in animal feed formulations?
☐ Firm does not manufacture feed. ☐ Yes ☒ No

a) If yes, does tallow used in ruminant feed contain not more than 0.15% insoluble impurities? ☐ Yes ☐ No

3. Does the firm receive feeds or feed ingredients that contain or may contain prohibited material (PM)? ***(Check only one)***
☐ YES, but PM is *Only* in Retail Pet/Lab Feed ☐ Yes ☒ No

a) **If Question 3 is "YES, but PM is only in Retail Pet/Lab Feed"** or "NO," check all of the following that describe ***voluntary*** safeguards the firm has in place to assure they do not receive prohibited material.

☒ Written assurance from ***suppliers*** that they no longer manufacture/distribute any products containing prohibited materials
☐ Written assurance from ***transporters*** that they do not transport products containing prohibited materials
☐ Written assurance from ***transporters*** that they utilize dedicated transport equipment OR utilize clean-out measures that adequately prevent commingling or cross-contamination
☒ Written procedures for the label review of incoming materials
☐ Uses only vegetable source proteins and uses no animal proteins
☒ Uses animal proteins only from ***exempted*** sources ***(Check all that apply)***
☐ Blood ☐ "Plate waste" ☐ Equine ☐ Fish
☐ Milk ☒ Porcine ☐ Poultry ☐ Gelatin

☐ Testing of incoming materials *(Please describe)*

F) FORMULAS

5☒ 1. Formulas are reviewed for safety, regulatory compliance, and suitability for the intended species and specific class of Animal.

1☒ 2. Formulas are reviewed for compatibility with equipment limitations.

1☒ 3. A clear chain of custody and control of formulas exists between formulators and mixers.

3☒ 4. Formulas are clearly identified and maintained to ensure correspondence with current labeling.

5☒ 5. Formulas are accurate to produce commercial feed as indicated by its labeling.
(Note – check several formulas and labels for accuracy)

6. List person(s) responsible for formulation. NICE HARTOG

G) LABELS

1☒ 1. Feed labels are reviewed prior to use and initialed by responsible individual.

1☒ 2. Responsibility for the use of new labels and destruction of outdated labels is clearly allocated.

5☒ 3. A label is affixed to, or accompanies, all commercial feeds being distributed.

5☒ 4. Labels contain a list of ingredients and all guarantees required by law.

5☒ 5. Medicated feeds are clearly identified.

5☒ 6. Drug levels are guaranteed at Federally approved levels and are approved for the intended species/class of animal.

5☒ 7. Applicable warning statements as required by law are present and prominent (i.e. BSE, drugs, NPN, and selenium).

5☒ 8. Feeding and/or mixing directions are adequate for the safe, approved and intended use of the commercial feed.

9. List person(s) responsible for designing feed labels. _____

H) PRODUCTION RECORDS

1. Mixing records are maintained to chronicle sequence and quantity of batches produced daily.

1☐ A. Provide a complete and traceable history of the production of a batch or production run.

1☐ B. Written endorsement by a responsible person.

1☐ C. Name and quantity of drug or high-risk components used.

5☒ 2. Acceptable deviations of actual from theoretical batch weights have been determined.

5☒ 3. A comparison of theoretical versus actual production batch weights are recorded.

5☒ 4. A comparison of actual production versus final load weight or bag count is documented.

3☒ 5. Production records include a code or lot number that identifies every load of feed manufactured for at least one year.

3☒ 6. Production records are reviewed daily and management is immediately notified of any discrepancies.

5☒ 7. Significant discrepancies are investigated and the production records show the corrective actions taken.

5☒ 8. The production formula agrees with the formula in the master record file.

I) LABORATORY ANALYSES OF FINISHED FEED

5☒ 1. Medicated feeds are analyzed at least once per year for each drug in use, three times per year for Category II type A.

5☒ 2. All out of tolerance assay results are investigated to verify that formulation and manufacturing processes are in control.

1☒ 3. Corrective actions are documented.

145 POINTS OUT OF 150 POSSIBLE

96.7%

MICHAEL DAVIDSON - SENIOR SPECIAL INVESTIGATOR