IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, Plaintiff, v. DAN NOLAN LIVESTOCK, L.L.C., a corporation, and DANIEL W. NOLAN, individual Defendants.	)	CIVIL ACTION NO. 12-C-643

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Dan Nolan Livestock, L.L.C., and individual Daniel W. Nolan ("Defendants"), and Defendants, having appeared and consented to the entry of this Consent Decree of Permanent Injunction ("Decree") without contest, without admitting or denying the allegations of the Complaint, and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter of this action and personal jurisdiction over all parties to this action pursuant to 28 U.S.C. § 1345 and 21 U.S.C. § 332,

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. ("the Act").

3. The Complaint alleges that the Defendants violate the Act, 21 U.S.C. § 331(a), by introducing and causing to be introduced into interstate commerce, and delivering and causing to be delivered for introduction into interstate commerce, food that is adulterated within the meaning of 21 U.S.C. §§ 342(a) (2) (C) (ii) and 342(a) (4). Defendants violate 21 U.S.C.

§ 331(k), by causing new animal drugs to become misbranded within the meaning of 21 U.S.C. § 353(f) (1) while such drugs are held for sale after shipment in interstate commerce. Defendants violate 21 U.S.C. § 331(k), by adulterating and causing the adulteration, within the meaning of 21 U.S.C. § 351(a) (5), of new animal drugs while such drugs are held for sale after shipment in interstate commerce. Defendants also violate 21 U.S.C. § 331(u) by failing to comply with the requirements in 21 U.S.C. § 360b(a) (4) (A) regarding the extra-label use of new animal drugs.

4. Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them who have received notice of this Decree, are hereby permanently restrained and enjoined, under 21 U.S.C. § 332(a), and the equitable authority of this Court, from directly or indirectly introducing or causing to be introduced into interstate commerce, and/or delivering or causing to be delivered for introduction into interstate commerce, any article of food, within the meaning of 21 U.S.C. § 321(f), and/or administering to animals any drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), while such drugs are held for sale after shipment in interstate commerce, unless and until:

A. Defendants establish and implement a system that ensures that each of the animals that they acquire, purchase, hold, transport, sell, consign, or lease is individually and permanently identified by tag number;

B. Defendants establish and implement a written record-keeping system that prevents them from selling, consigning, leasing, and/or distributing any animals whose edible tissues contain new animal drugs in amounts above the levels permitted by law. This system shall include, but not necessarily be limited to, keeping written records on every animal to which Defendants administer drugs.

These records shall include: (1) the identity of each animal Defendants medicate; (2) the date each drug is administered to each animal; (3) the identity of each drug administered; (4)

the dosage of each drug used; (5) the route of administration of each drug used; (6) the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship for each drug used, if applicable; (7) the name of the person who administers each drug; (8) the proper withdrawal period for each drug administered; (9) the date such withdrawal period will terminate for each drug administered; (10) the date each medicated animal is shipped for slaughter or leaves Defendants' control; and (11) the name and address of the purchaser, receiver, lessee, or consignee of each medicated animal that is shipped for slaughter or leaves Defendants' control;

C. Defendants establish and implement a system that ensures that their use of new animal drugs conforms to the uses approved by the United States Food and Drug Administration (“FDA") and set forth in each drug's approved labeling or, for new animal drugs used in an extra-label manner, to the lawful written order of a licensed veterinarian in accordance with 21 U.S.C. § 360b(a) (4) (A), provided that order does not result in illegal residues.

This system shall include measures to ensure that the following shall not occur:

(1) administering drugs in excess of the approved dosage, unless the extra-label use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a) (4) (A) and 21 C.F.R. § 530;

(2) selling or delivering medicated animals for slaughter before the expiration of the relevant withdrawal period for any drug with which the animals have been treated;

(3) using unapproved drugs in Defendants' animals unless, for new animal drugs, such extra-label use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C. § 360b(a) (4) (A) and 21 C.F.R. § 530; and

(4) administering new animal drugs by a non-approved route, unless such extra-label use is in accordance with the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship and is in compliance with 21 U.S.C, § 360b(a) (4) (A) and 21 C.F.R. § 530;

D. Defendants establish and implement a drug inventory and accountability system that prevents them from selling, consigning, leasing, and/or delivering any animals with illegal new animal drug residues in their edible tissues. This system shall include a written record for each drug that Defendants purchase or receive for use in medicating any of their animals.

These records shall include, but not necessarily be limited to: (1) the name of the drug; (2) the date of purchase or receipt of the drug; (3) the quantity, strength, and form of the drug purchased or received; (4) the expiration date of the drug purchased or received; (5) the name and address of the supplier or seller of the drug; (6) the date each drug is administered; and (7) the amount and method of each administration of each drug. In addition, the inventory and accountability system shall include periodic checks of inventory and records, no less frequently than once every thirty (30) calendar days, to ensure that the records accurately document the drugs currently on hand and the disposition of all drugs purchased or received, including whether the drugs have been administered;

E. Defendants establish and implement a system that ensures ready distinction between medicated and unmedicated animals and that prevents Defendants from selling, consigning, leasing, and delivering for slaughter for use as food any animals with illegal new animal drug residues in their edible tissues;

F. Defendants establish and implement a system that ensures that each animal that has been medicated is not directly or indirectly sold, consigned, leased, or delivered for immediate or ultimate slaughter until the withdrawal period (specified in the drug's approved labeling or, for new animal drugs used in an extra-label manner, in the lawful written order of a

licensed veterinarian made in accordance with 21 U.S.C. § 360b(a) (4) (A) for each drug used on such animal, has expired.

This system shall also ensure that each purchaser, receiver, lessee, or consignee receives, prior to accepting any animal, (a) a written statement from Defendants certifying that any animal that has been medicated has also been withdrawn from drugs for the appropriate time period, (b) a written statement that the animal has been medicated, each drug with which the animal was treated, the date the animal was treated with each drug, the required withdrawal period for each drug, and the date(s) on which the withdrawal period(s) will expire, or (c) a written statement that the animal has not been medicated. Defendants shall, prior to selling, leasing, or otherwise transferring any animal, obtain the signature of the purchaser, receiver, lessee, or consignee documenting date of receipt of the statement from Defendants. Defendants shall keep, as part of their records, a copy of the signed written statement described in this Paragraph;

G. Defendants shall establish and implement a system that identifies the source of each animal that they purchase or otherwise receive and ensure that Defendants obtain the following document(s) prior to taking possession of any animal:

(1) A signed written statement from the seller, transferor, or auction house certifying that the animal does not have illegal drug residues, or

(2) A signed written statement from the seller, transferor, or auction house identifying the name of each drug administered to the animal, the date each such drug was administered to the animal, and the date on which the withdrawal period will expire.

Defendants shall keep, as part of their records, a copy of the document(s) described in this Paragraph;

H. Defendants have reported to FDA in writing the steps they have taken to comply with Paragraphs 4 (A) - (G);

I. FDA has inspected Defendants' operations, including the records relating to the medication, purchase, sale, consignment, and distribution of food-producing animals. Such inspection will take place within thirty (30) business days after receiving Defendants' report required by Paragraph 4(H) and any other materials FDA requires to evaluate Defendants' operations;

J. Defendants have paid for the costs of the inspections at the rates specified in Paragraph 13; and

K. FDA has notified Defendants in writing that they appear to be in compliance with the requirements of Paragraphs 4 (A)-(J) of this Decree.

5. Prior to obtaining written notification of compliance from FDA as specified in Paragraph 4 (K), Defendants may administer drugs as prescribed to an ill, food-producing animal that they own and that is located on their farm, but only after the animal has been examined by a licensed veterinarian and that veterinarian has diagnosed and prescribed the particular drug for that animal. Defendants shall maintain copies of the veterinarian's diagnosis, prescription, and receipts for treatment or the equivalent, and provide those to FDA upon request.

6. Defendants shall maintain all records described in Paragraphs 4 (B), 4 (F) and 4 (G) for at least two (2) years after the date that Defendants sell, consign, deliver, or lease the animal. These records shall be made available to FDA upon request for purposes of inspection and copying.

7. Within fifteen (15) calendar days after the entry of this Decree, Defendants shall: (a) provide a copy of the Decree, by personal service or by certified mail, return receipt requested, to each and all of Defendants' agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, including any veterinarians from whom Defendants receive new animal drugs, and all persons to whom Defendants have sold, consigned, or delivered any cattle or calves for slaughter within

one year preceding the date of entry of the Decree; and (b) explain the terms of the Decree to each employee.

8. Within twenty (20) calendar days after the entry of this Decree, Defendants shall provide the Director, FDA Minneapolis District Officer at the address set forth in Paragraph 17, and to Plaintiff's attorneys, an affidavit from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with Paragraph 7 and identifying the names and positions of all persons who were notified pursuant to Paragraph 7.

9. After entry of the Decree, Defendants shall, within three (3) calendar days of hiring of any new employee at Defendants' operations: (a) provide a copy of the Decree, by personal service or by certified mail return receipt requested, to all such employees; and (b) explain the terms of the Decree to all such employees.

10. After Defendants receive FDA's written notification as described in Paragraph 4 (K), their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with them, are permanently restrained and enjoined from directly or indirectly doing and/or causing to be done any of the following acts;

A. Introducing or delivering for introduction into interstate commerce any article of food, within the meaning of 21 U.S.C. § 321(f), that is adulterated within the meaning of 21 U.S.C. §§ 342 (a) (2) (C) (ii) or 342 (a) (4);

B. Administering to any food-producing animal any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), unless such administration is in a manner that conforms to such drug's labeled indications and conditions for use or, for new animal drugs used in an extra-label manner, such administration is by or on the lawful written order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, does not result in an illegal drug residue, and is otherwise in compliance with 21 U.S.C. § 360b(a) (4) (A) and 21 C.F.R. § 530;

C. Dispensing any new animal drug, as defined in 21 U.S.C. § 321(v), while such drugs are held for sale after shipment in interstate commerce that results in such drug being misbranded within the meaning of 21 U.S.C. § 353(f) (1);

D. Doing any act with respect to any article of drug, including, but not limited to, any new animal drug, as defined in 21 U.S.C. § 321(v), if such act is done while such drug is held for sale after shipment in interstate commerce and results in such drug being adulterated within the meaning of 21 U.S.C. § 351 (a) (5); and/or

E. Failing to implement and continuously maintain the requirements of this Decree.

11. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' operations, including any new locations, and any facility or location at which Defendants hold or store animals and/or drugs used to treat animals, including food-producing animals and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. Such inspections may, at FDA's discretion, include the taking of photographs and samples and the examination and copying of all records that relate to drug administration and the holding, delivery, sale, consignment, or distribution of food-producing animals at any facility or location Defendants operate, manage, or control. Such inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

12. Upon request, Defendants shall promptly provide any information and records to FDA regarding the sale, consignment, delivery, or medication of any animals.

13. Defendants shall reimburse FDA for the costs of conducting and evaluating all inspection, laboratory, analytical, and other work that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date of entry of this Decree, these rates are: $87.57

per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $104.96 per hour and fraction thereof per representative for laboratory and analytical work; 55.5 cents per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed, per representative, for subsistence expenses where necessary. In the event that the standard rates generally applicable to the FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

14. If Defendants violate this Decree and are found in civil or criminal contempt thereof, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, investigational and analytical expenses, and court costs relating to such contempt proceedings.

15. If, based on the results of any inspection or analysis conducted after the inspection described in Paragraph 4 (I), or any other information, FDA finds that Defendants are not in compliance with this Decree, the Act, and all applicable regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the non-compliance and may require that Defendants immediately take one or more of the following actions;

A. Cease selling and delivering, and causing to be sold and delivered, any article of food within the meaning of 21 U.S.C. § 321(f);

B. Cease medicating animals in a manner inconsistent with a drug's labeled indications and conditions for use or the lawful written order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship and FDA's regulations set forth in 21 C.F.R. § 530; and/or

C. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and all applicable regulations.

Upon receipt of such notification, Defendants shall immediately and fully comply with the terms of the notice. Any cessation of operations or other action ordered by FDA as described above shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with the terms of this Decree, the Act, and all applicable regulations.

16. Defendants shall notify FDA at least thirty (30) calendar days before any change in ownership, name, or character of the business that occurs after the entry of this Decree, such as reorganization, relocation, assignment, or sale of the business that may affect compliance obligations arising out of this Decree, Defendants shall serve a copy of this Decree on any prospective successor or assignee at least thirty (30) calendar days prior to such sale or change of business, and shall furnish to FDA an affidavit of compliance with this Paragraph within fifteen (15) calendar days of such sale or change of business.

17. No sooner than 60 months after entry of this Decree, Defendants may petition this Court for an Order to dissolve this Decree. If Defendants have maintained, to FDA's satisfaction, a state of continuous compliance with this Decree, the Act, and all applicable regulations during the 60 months preceding Defendant's petition, the United States will not oppose such petition.

18. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be submitted to the Director, FDA Minneapolis District Office, 250 Marquette Avenue, Suite 600, Minneapolis, MN 55401.

19. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2) (A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

20. If any Defendant fails to comply with the provisions of this Decree, that Defendant shall pay to the United States of America liquidated damages in the sum of one

thousand dollars ($1,000.00) for each day that Defendant fails to comply with this Decree and an additional one thousand dollars ($1,000.00) for each drug that Defendant dispenses and each animal that Defendant sells or delivers for sale in violation of this Decree. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and that they do not in any way limit the ability of Plaintiff to seek, and the Court to impose, additional criminal or civil contempt penalties based on conduct that may also be the basis for the payment of liquidated damages.

21. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

SO ORDERED this 9th day of July, 2012.

/S WILLIAM C. GRIESBACH
U.S. DISTRICT COURT JUDGE

Entry consented to by:

FOR DEFENDANTS

/s/ Daniel W. Nolan
DANIEL W. NOLAN, individually and
on behalf of Dan Nolan Livestock, L.L.C.

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