BENJAMIN B. WAGNER
United States Attorney
CATHERINE J. SWANN
Assistant United States Attorney
501 I Street, 10th Floor
Sacramento, California 95814
Telephone: (916) 554-2762
Fax: (916) 554-2900

TONY WEST
Assistant Attorney General
KENNETH L. JOST
Acting Director, Office of
Consumer Protection Litigation
DANIEL M. BAEZA
Trial Attorney
Office of Consumer Protection Litigation
Virginia Bar #74645
United States Department of Justice
Liberty Square Building - Room 6400 South
450 Fifth St., NW
Washington, DC 20001
Telephone: (202) 616-4916
Facsimile: (202) 514-8742
E-Mail: dan.baeza@usdoj.gov
Attorneys for the United States of America

UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF CALIFORNIA
SACRAMENTO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. JOHN C. VIRTUE, an individual, doing business as VIRTUE CALVES, a sole proprietorship, and SHANNON L. VIRTUE, an individual, Defendants.	Civil No. 2:11-cv-1682-GEB-CMK CONSENT DECREE OF PERMANENT INJUNCTION

The United States of America, having filed a Complaint for Permanent Injunction against John C. Virtue, an individual doing business as Virtue Calves, and Shannon L. Virtue, an individual ("defendants"), and defendants, having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America having consented to the Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The Complaint states a cause of action against defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301-397.

3. Defendants violate the Act, 21 U.S.C. § 331(a) by introducing and delivering for introduction into interstate commerce food within the meaning of 21 U.S.C. § 321(f), namely veal calves and their edible tissues, that are adulterated within the meaning of 21 U.S.C. § 342(a)(2)(C)(ii), in that they contain unsafe new animal drugs, and 21 U.S.C. § 342(a)(4), in that defendants hold food under insanitary conditions whereby it may have been rendered injurious to health.

4. Defendants and each and all of their agents, representatives, employees, attorneys, heirs, assigns, successors, and any and all persons in active concert or participation with any of them (collectively, "Associated Persons") with notice of this Decree, are permanently restrained and enjoined pursuant to 21 U.S.C. § 332(a) and the equitable authority of this Court from directly or indirectly introducing and causing to be introduced and delivering for introduction into interstate commerce any food within the meaning of 21 U.S.C. § 321(f), consisting of animals or their edible tissues, unless and until all of the following occur:

(a) Defendants establish a written record-keeping system (the "written record") in which they permanently and individually identify each animal purchased, held, transported, consigned, or sold. The information contained in the written record shall include, at a minimum:

(1) the date the animal was purchased or obtained;

(2) the name and complete address of the seller;

(3) the tag number of the animal or, if the animal does not have a tag number at the time of purchase by defendants, defendants shall, upon purchase, place a tag number or other identifier on the animal and record it in the written record;

(4) the date defendants sold, consigned, distributed, transported, or delivered the animal for slaughter or otherwise disposed of it; and

(5) the name and complete address of the seller, consignee, or receiver of the animal;

(b) Defendants establish a system whereby, for each animal purchased that is intended for slaughter or may be sent to slaughter, defendants determine whether the animal has been medicated, been fed medicated feed, or been fed milk or colostrum from a medicated animal. Defendants shall make such determination by requesting and reviewing all records maintained by the seller and obtaining a signed written statement from the seller that indicates the medication status of the animal. Defendants shall identify a medicated animal in their written record by stating that the animal is medicated and a non-medicated animal by stating that the animal is non-medicated and shall record, in the written record, the name of the person who provided information about the animal's medication status. For each animal that is medicated, defendants shall also obtain the following information from the seller and record such information in the written record:

(1) the date of each administration of medication or feeding of medicated feed, milk, or colostrum;

(2) the name and dosage of the drug or medicated feed used;

(3) the route of administration of the drug; and

(4) whether and when the withdrawal period has expired or will expire;

(c) Defendants establish a system to segregate medicated and non-medicated animals they hold that ensures defendants will not sell, consign, or deliver for slaughter any animal that may contain illegal residues of new animal drugs;

(d) Defendants establish a system whereby prior to sale, consignment, or delivery of any animal to any person or entity who may send such animal to slaughter at any time, they provide to the purchaser, receiver, or consignee of the animal a signed written statement stating whether the animal has been medicated or fed medicated feed or milk or colostrum from a medicated animal. If so medicated, the signed written statement shall also state:

(1) the date of each administration of medication or feeding of medicated feed, milk, or colostrum;

(2) the name and dosage of the drug or medicated feed used;

(3) the route of administration of the drug; and

(4) whether and when the withdrawal period has expired or will expire.

This system shall ensure that no animal that may be slaughtered is sold by defendants unless the purchaser, receiver, or consignee is informed of the complete medication status of the animal. If the animal has not been medicated or fed milk or colostrum from a medicated animal, defendants shall provide a signed and dated written statement to the purchaser, receiver, or consignee declaring that the animal has not been medicated. Defendants shall also obtain the signature of the purchaser, receiver, or consignee documenting receipt of the signed and dated written statement from defendants;

(e) Defendants have reported to FDA in writing the steps taken to comply with paragraphs 4(a)-(d) above;

(f) FDA has inspected defendants' operations, including all records relating to defendants' purchase, transport, holding, sale, consignment, and distribution of animals; and

(g) FDA has notified defendants, in writing, that they appear to be in compliance with the requirements of paragraphs 4(a)-(d) of this Decree.

5. After receiving FDA approval pursuant to paragraph 4(g) above, defendants shall continuously implement the systems set forth in paragraph 4(a)-(d) above.

6. Defendants shall maintain the written record and all other records or statements described in paragraph 4 for each animal for a period of at least 3 years after the date the animal is sold, consigned, distributed, or delivered to any person or entity. Defendants shall make these records available to FDA immediately upon request for inspection and copying.

7. Within 15 calendar days after entry of this Decree, defendants shall provide a copy of the Decree, by personal service or, if necessary, by certified mail, return receipt requested, to Associated Persons and all persons to whom defendants have sold, consigned, or delivered any animals within one year preceding the date of entry of the Decree.

8. Within 20 calendar days after entry of this Decree, defendants shall provide the Director, FDA San Francisco Office, 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 6, and identifying the names and positions of all persons who were notified pursuant to paragraph 6.

9. After entry of the Decree, defendants shall, within 5 calendar days of hiring, engaging, or retaining any new employee, consultant, contractor, or person on a permanent or temporary basis, provide a copy of the Decree, by personal service or, if necessary, by certified mail, return receipt requested, to all such persons.

10. After defendants receive written notification from FDA as specified in paragraph 4(h) above, defendants and all Associated Persons are permanently restrained and enjoined from directly or indirectly doing or causing to be done any of the following acts:

(a) Introducing or delivering for introduction into interstate commerce animals for use as human food that are adulterated within the meaning of 21 U.S.C. §§ 342 (a)(2)(C)(ii) or 342 (a)(4);

(b) Failing to implement and continuously maintain each of the requirements of this Decree.

11. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect defendants' livestock operations, including any new locations, and to take any other measures necessary to monitor and ensure continuing compliance this Decree. Such inspections may, at FDA's sole discretion, include the taking of photographs and samples and the examination and copying of all records that relate to the purchase, holding, delivery, sale, consignment, or distribution of animals on the premises. FDA shall have permission to inspect by presenting a copy of this Decree and appropriate credentials. Such inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under 21 U.S.C. § 374.

12. Upon request, defendants shall promptly provide all information or records to FDA regarding the purchase, sale, consignment, holding, transport, delivery, or medication of any animals.

13. Defendants shall reimburse FDA for the costs of conducting and evaluating all inspectional, analytical, or other work that FDA deems necessary to evaluate defendants' compliance with 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 work; $104.96 per hour or fraction thereof per representative for analytical or review work; $.51 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, 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, defendants shall, in addition to other remedies, reimburse plaintiff for its attorneys' fees

(including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings.

15. If, based on the results of any inspection or analysis conducted by FDA or any other information, FDA finds that any defendant is not in compliance with the Act, FDA regulations, or this Decree, 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 or delivering, and causing to be sold or delivered, any article of food within the meaning of 21 U.S.C. 321(f);

(b) Take any corrective actions as FDA deems necessary to bring defendants into compliance with this Decree, the Act, and FDA 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 in writing at least 15 calendar days before any change in ownership, name, or character of the business, such as reorganization, relocation, dissolution, assignment, lease, or sale of the business or any other change that may affect compliance with this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least 30 calendar days before any such change in the business. Within 5 calendar days of providing a copy of this Decree to a prospective successor or assign, defendants shall provide FDA and plaintiff's attorneys with an affidavit signed by a person with personal knowledge of the facts stated therein, attesting to defendants' compliance with this paragraph.

17. If any defendant(s) fails to comply with any provision of this Decree, the Act, and/or its implementing regulations as determined by FDA in its sole discretion, then defendant(s) shall pay the United States Treasury as liquidated damages the sum of $1,000.00 for each day each such defendant(s) fails to comply with this Decree, the Act, and/or its implementing regulations

(e.g.,if two violations occur for two days, the liquidated damages for each defendant shall be $4,000.00), and an additional $5,000.00 for each animal that defendant(s) purchase, sell, consign, deliver, distribute or hold for sale in violation of this Decree, the Act, and/or its implementing regulations (e.g., if two animals are sold in violation of this Decree, the liquidated damages for each defendant shall be $10,000). 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 the United States to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for the payment of liquidated damages.

18. Defendants shall address all communications with FDA required under this Decree to Director Compliance Branch, United States Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California, 94502, and reference this civil action by case name and civil action number.

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

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

21. Except as provided otherwise in this Decree, the parties shall bear their own costs and attorneys' fees in this action.

22. This Court retains jurisdiction over this action to enforce or modify this Decree and to grant all additional relief as is necessary and appropriate.

SO ORDERED:

Dated: June 24, 2011

GARLAND E. BURRELL, JR.
United States District Judge

We hereby consent to the entry of this Decree:

FOR DEFENDANTS

s/ John C. Virtue
John C. Virtue
Individually and doing business as Virtue Calves

s/ Shannon L. Virtue
Shannon L. Virtue
Individually

FOR PLAINTIFF
BENJAMIN B. WAGNER
United States Attorney

BY:

s/ Catherine Swann
CATHERINE SWANN
Assistant United States Attorney

s/ Dan Baeza
DAN BAEZA
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice,
Civil Division
6th Floor South
450 Fifth Street, N.W.
Washington, DC 20001

OF COUNSEL:

WILLIAM B. SCHULTZ
Acting General Counsel
United States Department of Health and Human Services

RALPH S. TYLER
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation,
Food and Drug Division

KAREN C. CORALLO
Associate Chief Counsel
Food and Drug Division