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UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. FIVE ARTICLES OF DRUG, ACAM2000, VACCINIA VACCINE, LIVE, Defendants.	No. CV 17-1449 VERIFIED COMPLAINT FOR FORFEITURE 21 U.S.C. § 334 [F.D.A.]

The United States of America brings this claim against the defendants Five Articles of Drug, ACAM2000, Vaccinia Vaccine, Live, described more particularly below (the "defendant articles"), and alleges as follows:

JURISDICTION AND VENUE

1. This is a civil forfeiture action *in rem* brought pursuant to 21 U.S.C. § 334 to seize and condemn the defendant articles

because they are in violation of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 et seq.

2. This Court has jurisdiction over the matter under 28 U.S.C. § 1345 and 21 U.S.C. § 334, which provide the Court with jurisdiction over seizures commenced by the United States under the Act.

3. The defendant articles are located at the United States Food and Drug Administration, Pacific Southwest Food and Feed Laboratory, 19701 Fairchild, Irvine, California.

4. Venue lies in this district pursuant to 28 U.S.C. § 1395(b) because the defendant articles are located in this district.

PERSONS AND ENTITIES

5. The plaintiff is the United States of America.

6. The defendant articles are five (5) vials of ACAM2000 Vaccinia Vaccine, Live, Labeled, in part, "ACAM2000 Expires 17 Months From June 2017."

7. The United States requests that this Court issue a warrant for arrest *in rem* pursuant to Supplemental Rule for Certain Admiralty and Maritime Claims G(3)(b), which the United States will execute upon the defendant articles pursuant to Supplemental Rule G(3).

EVIDENCE SUPPORTING FORFEITURE

8. The defendant articles are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. The defendant articles are also biological products within the meaning of the Public Health Service Act, 42 U.S.C. § 262(i)(1). A product can be both a drug and a biological product, and such products are subject to the Act, including its misbranding provisions. *See* 42 U.S.C. § 262(j).

9. The defendant articles are also intended for use as components of another drug, as described in paragraph 12 below. Components of drugs are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(D).

10. The defendant articles were shipped in interstate commerce from outside the state of California to a facility in California.

11. ACAM2000 is an FDA-approved biological product for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. ACAM2000 is a live vaccinia vaccine that can be shed if lesions form on recipients, which can transfer viral infection to others in close contact. The only approved route of administration for ACAM2000 is the percutaneous route (scarification). ACAM2000's FDA-approved labeling expressly states that ACAM2000 "should not be injected by the intradermal, subcutaneous, intramuscular, or intravenous route." ACAM2000 is not approved to treat cancer, and is contraindicated for "[i]ndividuals with severe immunodeficiency," which often includes cancer patients. Before administering the drug, a droplet (0.0025 mL) of reconstituted vaccine is picked up with a bifurcated needle by dipping the needle into the ACAM2000 vial.

12. According to labeling, including but not limited to a protocol, the defendant articles are combined with autologous stromal vascular fraction ("SVF") derived from adipose (fat) tissue to treat patients suffering from a range of advanced stage cancers. The combined SVF/ACAM2000 is administered intravenously and intertumorally, with the ACAM2000 administered at several times the approved dose used for scarification of the skin.

13. The combined SVF/ACAM2000 is a new drug within the meaning of 21 U.S.C. § 321(p), because it is not generally recognized by

qualified experts as safe and effective under conditions of use recommended and suggested in its labeling.

14. The combined SVF/ACAM2000 is an unapproved new drug in that there are no approved applications for this drug, nor is it the subject of an investigational new drug application.

15. The defendant articles are misbranded within the meaning of the Act, 21 U.S.C. § 352(f)(1), because they are intended to be combined with SVF, the combination SVF/ACAM20000 is an unapproved new drug, and the ACAM2000 labeling does not bear adequate directions for that use. The defendant articles are not exempt from such requirement under 21 C.F.R. § 201.115, nor any other exemption in subpart D of Part 201. Moreover, any exemption that might otherwise apply ceased to exist under 21 C.F.R.§ 201.127(a), because the drugs were shipped for purposes beyond those that are specified in ACAM2000's approval.

16. The defendant articles are also misbranded because, as components of the unapproved SVF/ACAM2000, they are "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j).

17. Between July 17, 2017, and August 04, 2017, United States Food and Drug ("FDA") investigators conducted an inspection of StemImmune, Inc., located in San Diego, California. During the inspection, FDA investigators determined that StemImmune received a shipment of five vials of ACAM2000 Vaccinia Vaccine, Live, Lot #VV03-019-C, and identified a protocol for combining the ACAM2000 with SVF, as described in paragraph 12 above.

18. On July 28, 2017, the California Department of Public Health placed the defendant articles under embargo. The embargoed

articles were subsequently transported to FDA's Los Angeles District, as described in paragraph 3, where they remain.

19. By reason of the foregoing, the defendant articles are held illegally within the jurisdiction of this Court and are subject to seizure and condemnation pursuant to 21 U.S.C. § 334.

CLAIM FOR RELIEF

20. Based on the above, plaintiff alleges that the defendant articles are misbranded drugs that are held illegally within the jurisdiction of this Court and are liable to seizure, forfeiture, and condemnation pursuant to 21 U.S.C. § 334.

WHEREFORE, plaintiff United States of America prays:

(a) That the Court issue a warrant of arrest in rem for the United States Marshals Service for the Central District of California or any other duly authorized law enforcement officer to seize and maintain the defendant articles during the pendency of this action;

(b) that due process issue to enforce the forfeiture of the defendant articles;

(c) that due notice be given to all interested parties to appear and show cause why forfeiture should not be decreed;

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(d) that this Court decree forfeiture of the defendant articles to the United States of America for disposition according to law; and

(e) for such other and further relief as this Court may deem just and proper, together with the costs and disbursements of this action.

Dated: August 23, 2017

Respectfully submitted,

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Chief, Asset Forfeiture Section

/s/ Jonathan Galatzan
JONATHAN GALATZAN
Assistant United States Attorney

Attorneys for Plaintiff
UNITED STATES OF AMERICA

VERIFICATION

I, Daniel Cline, hereby declare that:

1. I am a Compliance Officer for the United States Food and Drug Administration, Department of Health and Human Services, and am assigned to the forfeiture manner captioned United States of America v. Five (5) articles of drug, ACAM2000, Vaccinia Vaccine, Live.

2. I have read the above Verified Complaint for Forfeiture *In Rem* and know its contents. It is based on my own personal knowledge and reports provided to me by other law enforcement agents.

3. Everything contained in the Complaint is true and correct, to the best of my knowledge and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Executed August 22, 2017, in Irvine California.

DANIEL CLINE