U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Vaccines, Blood & Biologics

March 26, 2012 Approval Letter - Avioq HTLV-I/II EIA/Lysate

Our STN: BL 125394/0

Avioq, Inc.
Attention: X. James Li, Ph.D.
104 TW Alexander Drive, Building 6
PO Box 12808
Research Triangle Park, NC 27709

Dear Dr. Li:

We are issuing Department of Health and Human Services U.S. License No. 1856 to Avioq, Inc., Research Triangle Park, NC under the provisions of section 351(a) of the Public Health Service Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product Human T-Lymphotropic Virus Types I & II (HTLV-I and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate). Human T-Lymphotropic Virus Types & II (HTLV-I and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate) is a qualitative enzyme-linked immunosorbent assay (ELISA) for the detection of antibodies to Human T-Lymphotropic Virus Type I (HTLV-I) and/or Human T-Lymphotropic Virus Type II (HTLV-II) in human serum or plasma. It is intended for screening individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti-HTLV-I/HTLV-II, and for use as an aid in clinical diagnosis of HTLV-I or HTLV-II infection and related diseases. It is also intended for use in testing serum and plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens. In addition to being used as a manual assay, the assay is also intended for use with the ORTHO® Summit System (OSS) fo screening blood donors.

Under this license, you are approved to manufacture Human T-Lymphotropic Virus Types I & II (HTLV- and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate) at your facility in Research Triangle Park NC. You may label your product with the proprietary name Avioq HTLV-I/II Microelisa System that we have approved, and market it as approved in your license application.

We did not refer your application to the Blood Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues which would have benefited from an advisory committee discussion.

The dating period for Human T-Lymphotropic Virus Types I & II (HTLV-I and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate) shall be 12 months from the date of manufacture when stored at the appropriate temperature required for each kit component. The expiration date for the packaged product, Avioq HTLV-I/II Microelisa System, shall be dependent on the shortest expiration date of any component.

Please submit final container samples of the product Avioq HTLV-I/II Microelisa System and each kit component in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center fo Biologics Evaluation and Research (CBER).

You must submit information to your biologics license application for our review and written approval

under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of Human T-Lymphotropic Virus Types I & II (HTLV-I and HTLV-II/Enzyme Immuno Assay (EIA)/Lysate), or in the manufacturing facilities.

You must submit reports of biological product deviations under 21 CFR 600.14. You promptly should identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA-3486 to the Director, Office of Compliance and Biologics Quality, Center for Biologics Evaluation and Research, HFM-600, 1401 Rockville Pike, Rockville, MD 20852-1448.

Please submit all final printed labeling at the time of use and include implementation information on Form FDA 356h. Please provide a PDF electronic copy as well as three original paper copies for circular and other labels.

In addition, two draft copies of the proposed introductory promotional labeling may be voluntarily submitted for advisory comment with a Form FDA 2253 to the Center for Biologics Evaluation and Research, Advertising and Promotional Labeling Branch, HFM-602, 1401 Rockville Pike, Rockville, MD 20852-1448.

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims [21 CFR 202.1(e)(6)].

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the Medical Device Reporting requirements for medical devices (21 CFR 803) as required by 21 CFR 600.80(k)(2). Since your product is characterized as a device as well as a biological, submit these reports to the MedWatch System using MedWatch Reporting Form 3500A. Required reports should be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting, P.O. Box 3002, Rockville, Maryland 20847-3002.

Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70.

We acknowledge your written commitment as described in your amendment of February 9, 2012 as outlined below:

----------(b)(4)---------- ----------

Please label the submission with the following designator: **Postmarketing Study Commitment – Final Study Report**

For a postmarketing commitment not subject to the reporting requirements of 21 CFR 610.70, you may report the status to FDA as a "PMC Submission – Status Update." The status report for each commitment should include:

- The original schedule for the commitment, and
- The status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted).

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Page Last Updated: 04/04/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page: