The Secretary of the 19th Expert Committee on the Selection and Use of Essential Medicines, Medicine Access and Rational Use
Department of Essential Medicines and Health Products
World Health Organization
20 Avenue Appia
CH-1211 Geneva 27
Switzerland
email: emlsecretariat@who.int

Dear Sir,

This communication is provided by the US Food and Drug Administration in support of an application submitted by AABB to request listing of Whole Blood and Red Blood Cells on the WHO Model List of Essential Medicines. Our Agency is of the opinion that a) Whole Blood and Red Blood Cells are medicines (identified as “drugs” within our system), and b) that they satisfy the priority health care needs of the population in all countries. The following information provides evidence that labile blood components, which include Whole Blood and Red Blood Cells, are regulated as drugs (i.e. medicines) in our jurisdiction.

In the United States of America, labile blood products (whole blood and blood components for use in transfusion) are regulated as biological products that are also considered to be drug products (i.e. medicines). The dual identity of these blood products as biological products and drugs stems from the application of two different laws: the Public Health Service Act, first passed as the Biologics Control Act of 1902, and the Federal Food, Drug, and Cosmetic Act, first passed in 1938. Both laws have been amended over time. Under these laws, labile blood products meet both the definition of a biological product and the definition of a drug. The term “biological product” expressly includes “blood, blood component or derivative . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” The term “drug” includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

Labile blood products must meet standards to assure their safety, purity, and potency (efficacy). These products are subject to current Good Manufacturing Practice regulations. FDA has issued specific regulations describing product standards, which address product quality, donor eligibility, and donor protection, as well as standard operating procedures and record retention. FDA developed these standards to address the particular manufacturing issues presented by the manufacture of labile blood products.

FDA also regulates the labeling of labile blood products. FDA regulations provide requirements for the product label. In addition, blood establishments must have available for distribution with the product an approved circular of information, which contains adequate directions for use.
FDA requires that labile blood products be licensed before they can be distributed in interstate commerce, and the agency first licensed a blood establishment to manufacture labile blood products in 1946. In support of a license application, blood establishments must provide information demonstrating that their facilities and blood collection and processing practices meet regulatory standards. Once licensed, applicants must notify FDA of changes to their blood processing practices. They cannot initiate changes that have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product without prior approval by FDA.

FDA inspects blood establishments every two years to assure that they are meeting standards for the manufacture of blood products – including collection, testing, storage, processing, distributing, and compatibility testing for blood products. FDA can use both the biological product and drug authorities for enforcement. These provide a mechanism for FDA to suspend or revoke licenses, to file suit in court to enjoin violative practices, or to seize violative blood products.

Thank you for your consideration of this information in the context of the application.

Sincerely,

Karen Midthun, M.D.
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration