



Our STN: BL 102010/5041

January 31, 2007

Indiana Blood Center
Attn: Kerry Mettert
3450 North Meridian Street
Indianapolis, IN 46208

Dear Mr. Mettert:

We have been advised by your letter dated October 20, 2006, that your establishment formerly identified as Central Indiana Regional Blood Center, Inc., U.S. License Number 0398, is now identified as Indiana Blood Center.

It is our understanding that Indiana Blood Center will continue to prepare the following products in the same manner as Central Indiana Regional Blood Center, Inc., using the same equipment, manufacturing procedures and methods, and responsible personnel:

- Whole Blood
- Red Blood Cells
- Platelets
- Plasma
- Cryoprecipitated AHF
- Source Leukocytes

Therefore, in accordance with the provisions of Title 21 Code of Federal Regulations 601.5(a), Establishment License No. 0398 and the Product Licenses for the products noted above are hereby revoked, effective this date.

In addition, in accordance with the provisions of Section 351(a) of the Public Health Service Act, U.S. License Number 1759 is hereby issued to Indiana Blood Center, Indianapolis, Indiana, effective this date.

This license authorizes you to manufacture and introduce or deliver for introduction into interstate commerce, those products for which you have demonstrated compliance with establishment and product standards. Under this license, you are authorized to manufacture and introduce or deliver for introduction into interstate commerce Whole Blood and blood components at the following locations.

- 3450 North Meridian Street, Indianapolis, IN 46208 (Registration No. 1873403)
- 2200 Elmwood Ave. Suite D 16, Lafayette, IN 47904 (Registration No. 1828129)
- 1826 S. Scatterfield Road, Anderson, IN 46016 (Registration No. 1828989)

- 6620 Parkdale Place, Suite J, Indianapolis, IN 46254 (Registration No. 1828990)
- 1414 South Range Line Road, Carmel, IN 46032 (Registration No. 1831154)
- 2021 South 3rd Street, Terre Haute, IN 47802 (Registration No. 1876566)
- 8725 U.S. 31 S, Indianapolis, IN 46227 (Registration No. 1876571)
- 10537 E. Washington St., Unit E-2, Indianapolis, IN 46229 (Registration No. 1876573)
- 1435 N. National Road, Columbus, IN 47201 (Registration No. 3000204211)
- 2113 E. Maxwell Avenue, Evansville, IN 47711 (Registration No. 3000718513)
- 7458 E. Fishers Station, Fishers, IN 46038 (Registration No. 3003103607)
- 3728 S. Reed Road, Kokomo, IN 46902 (Registration No. 3003841989)
- 1630 East State Road 44, Shelbyville, IN 46176 (Registration No. 3004357220)
- 7655 East US Highway 36, Avon, IN 46123 (Registration No. 3004582741)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled applicable requirements for this supplement to an application.

All pending supplements submitted under U.S. License Number 0398 have been transferred to U.S. License Number 1759. All future correspondence for these submissions should be submitted under the originally assigned Submission Tracking Numbers.

We will include information contained in the above-referenced supplement in your biologics license application files.

Sincerely yours,



for Alan E. Williams, Ph.D.
Director
Division of Blood Applications
Office of Blood Research and Review
Center for Biologics
Evaluation and Research