

# **Guidance for Industry**

## **Variations for Blood Collection from Individuals with Hereditary Hemochromatosis**

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Biologics Evaluation and Research (CBER)  
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## GUIDANCE FOR INDUSTRY

### Variations for Blood Collection from Individuals with Hereditary Hemochromatosis

*This guidance document represents FDA's current thinking on the distribution of blood and blood components from individuals with hereditary hemochromatosis without disease labeling, and collecting blood more frequently than every eight weeks without a physical examination on the day of donation. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.*

#### I. PURPOSE

This guidance document provides recommendations to you, blood establishments, that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disorder on the container label. This guidance also provides recommendations if you wish to collect blood from such individuals more frequently than every eight weeks without a physical examination and certification of the donor's health by a physician on the day of donation. This document identifies conditions under which we, FDA, will consider approving the above as alternative procedures, or variances, to the current regulations, under the provisions of Title 21, Code of Federal Regulations, Section 640.120 (21 CFR 640.120). It also provides guidance on what you should submit to us when requesting these variances. These recommendations apply to all blood establishments, whether or not you hold a U.S. License for the manufacture of blood and blood components.

#### II. INTRODUCTION

Hereditary hemochromatosis (HH) is an inherited disorder of iron metabolism, with an estimated prevalence of 0.25-0.50% among Caucasians. An epidemiologic study is currently underway to determine the prevalence, as well as the genetic and environmental determinants, of iron overload related to hereditary hemochromatosis in a multiethnic population. This iron metabolism disorder often results in the deposition of excess iron in body tissues that can reach toxic levels leading to organ damage. The toxicity can affect most tissues and organs, but particularly the liver, endocrine organs, and the heart. Early initiation of therapeutic phlebotomy before organ damage occurs may restore a normal life expectancy and improve symptoms. (Ref. 1, 2)

Treatment of HH typically has two phases. First, the patient undergoes iron depletion therapy, in which excess iron is removed. In one study of current practices, two to three units of blood were withdrawn per month, for approximately one year. In the second phase, maintenance therapy, an average of one unit was withdrawn every two months. In the same study, 76% of respondents

reported full or partial insurance coverage of therapeutic phlebotomy charges. Charges ranged from a mean of \$48 for home phlebotomy, \$52 for blood centers, \$69 for physician's offices, to \$90 for hospitals. (Ref. 3)

On the basis of the currently understood molecular mechanisms of disease, there is no evidence that blood from HH patients would carry any added risk for transfusion recipients from HH. In addition, there is no evidence to support a transfer of a genetic disorder by transfusion. Blood from HH patients has been used for transfusion in other countries without reports of adverse reactions in recipients. (Ref. 2)

Currently, FDA does not prohibit the use of blood from therapeutic bleedings, but requires that blood intended for transfusion be labeled with the donor's disease (21 CFR 640.3(d)). In addition, the regulations state that a person may donate a unit of blood more than once in eight weeks only after a physical examination and certification of health by a physician (21 CFR 640.3(f)).

Many blood establishments that collect blood during a therapeutic phlebotomy have not routinely distributed this blood for transfusion, because consignees have refused to accept blood that is labeled with a disease. Thus, the labeling requirement is considered to be a barrier to the use of blood from HH donors for transfusion, despite evidence that this blood is safe.

There have been several studies that have shown an increase in the prevalence of bloodborne viral pathogens in blood obtained from paid donors as compared to volunteer donors. Therefore, there is concern about creating an incentive for HH patients to donate blood for free, rather than pay for a therapeutic phlebotomy. If a blood establishment charged a fee for therapeutic phlebotomy, but not for a blood donation for transfusion, the HH donor would have an incentive to deny risk conditions that might preclude cost-free donation. In this circumstance, blood donation provides indirect compensation for medical phlebotomy. (Ref. 4)

### **III. BACKGROUND**

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) "create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy" from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disorder. Further, ACBSA recommended that DHHS "create policies that eliminate barriers to using this resource" to augment the country's blood supply. (Ref. 5)

On August 10, 1999, the Commissioner of Food and Drugs made a commitment to consider case-by-case exemptions to existing blood labeling and donor suitability regulations for blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient (Ref. 6). The Commissioner wrote that as part of any exemption, we would request that safety data be collected and submitted to the Agency and that this data would be compared with data gathered on the general donor pool.

Additionally, we made a commitment to work with the Health Care Financing Administration (HCFA) in ensuring that the financial incentives for persons with HH to donate blood for transfusion are removed. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999. For the foreseeable future, if you wish to distribute blood collected from donors with HH without disease labeling, you will have the responsibility of removing financial incentives for these donors. You will have to evaluate the advantages of entering these donors into your donor pool. (Ref. 7, 8)

#### **IV. CONTENT OF VARIANCE REQUESTS**

We will consider requests for variances to the labeling and physician examination regulations. We believe that variances incorporating the following provisions would be acceptable.

- A. Blood donors with HH would meet the same suitability requirements as other donors (21 CFR 640.3(d)).
- B. To collect blood products from a donor with HH more frequently than every eight weeks you would:
  - 1. collect blood products from a donor who has presented a physician's prescription (bearing instructions regarding frequency of phlebotomy and hematocrit/hemoglobin limits) for therapeutic phlebotomy for HH; or,
  - 2. have your physician examine and certify the good health of the donor on the day of donation in accordance with 21 CFR 640.3(f) if you do not have a prescription on file for the donor's therapeutic phlebotomy for HH.
- C. You would not charge a fee for phlebotomies performed on any individuals with HH, including those who do not meet allogeneic donor suitability requirements at the initial or subsequent donations. At the initial donation, you would obtain the donor's written acknowledgement that the donor understands that you are providing therapeutic phlebotomy free of charge even if the donor is ineligible as an allogeneic blood donor. We note that you are required to maintain health history records of donors (21 CFR 606.160(b)(1)), and we would expect this health history to include diagnoses of HH.

#### **V. SUBMISSION OF VARIANCE REQUESTS**

- A. In accordance with 21 CFR 640.120, you must not implement changes at variance to the regulations prior to receiving approval from us.
- B. To obtain approval for a variance to 21 CFR 640.3(d) (labeling with the donor's disease) under the provisions of 21 CFR 640.120, you must submit a written request to us to omit HH labeling. You should include a statement that HH individuals whose blood will be used for transfusion will meet your allogeneic donor suitability criteria. You should also include a copy of the donor acknowledgement form (informed consent or other written statement), to be signed by the donor, that she/he will not be charged a fee for the phlebotomy even if found to be ineligible as an allogeneic blood donor.

- C. To obtain approval for a variance to 21 CFR 640.3(f) (physician examination) under the provisions of 21 CFR 640.120, you must submit a written request to collect blood products from donors with HH more frequently than every 8 weeks without examination by a physician at the time of donation. The submission should include statements that you are requiring a physician's prescription for therapeutic phlebotomy for HH, and that your physician would examine previously diagnosed HH donors without a prescription on the day of donation if less than 8 weeks have elapsed since the last donation.
- D. You may request these variances concurrently.
- E. If you hold a U.S License, you must submit variance requests as major changes (prior approval supplements) pursuant to 21 CFR 601.12(b). If you do not hold a U.S. License, you are not subject to 21 CFR 601.12, but are still required to obtain approval of variance requests before implementing changes at variance with the regulations.
- F. If you discontinue operating under the terms of the approved variance (e.g., start charging a fee for therapeutic phlebotomies for HH donors who do or do not meet allogeneic donor suitability criteria), the variance is no longer in effect and you must comply with the current regulations. You should notify us of this change in writing. If you hold a U.S. License, include this notification in your Annual Report.

## VI. REFERENCES

1. Iron Overload and Hereditary Hemochromatosis Study. RFP No. NIH-NHLBI-HC99-19, July 12, 1999. <http://www.nhlbi.nih.gov/funding/inits/archive/rfp99-19.htm>
2. Jeffrey G, Adams PC. Blood from patients with hereditary hemochromatosis-a wasted resource? *Transfusion* 1999;39:549-550.
3. McDonnell SM, Grindon AJ, Preston BL, Barton JC, Edwards CQ, Adams PC. A survey of phlebotomy among persons with hemochromatosis. *Transfusion* 1999;39:651-656. Title 21, Code of Federal Regulations, Parts 600-799.
4. Tan L, Khan MK, Hawk III JC. Use of blood therapeutically drawn from hemochromatosis patients. *Transfusion* 1999;39:1018-1026.
5. Nightingale SD, Summary of Advisory Committee Meeting of April 29 and 30, 1999, May 13, 1999. <http://www.hhs.gov/partner/bloodsafety/04-99sum.html>
6. Henney JE, Memorandum: Blood Donations by Individuals with Hemochromatosis, August 10, 1999. <http://www.hhs.gov/partner/bloodsafety/JEH8-10.jpg>
7. Nightingale S, Advisory Committee on Blood Safety and Availability, Ninth Meeting, August 26, 1999. [http://www.hhs.gov/partner/bloodsafety/Aug26\\_99.html](http://www.hhs.gov/partner/bloodsafety/Aug26_99.html)
8. Blood Products Advisory Committee, 64<sup>th</sup> Meeting, September 16, 1999. <http://www.fda.gov/ohrms/dockets/ac/cber99.htm> - Blood Products Advisory Committee

# Variances for Collection of Blood and Blood Products from Patients with Hemochromatosis

Following is a list of establishments granted approval for a variance to 21CFR640.3(d) and 21CFR640.3(f) in order to collect blood and blood products from patients with hemochromatosis. The approved variances are updated as of November 28, 2006.

Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis - 8/22/2001

| Name of Facility                                     | Address  | Licensed | Registered-Only | Approvals |           | Approval Date                |
|--|--|----------|-----------------|-----------|-----------|------------------------------|
|  |  |          |                 | 640.3 (d) | 640.3 (f) |                              |
| American National Red Cross                          | 3131 N Vancouver Ave<br>Portland, OR 97227<br>503-284-1234     | X        |                 | X         | X         | 3/28/2005                    |
| Anna Jaques Hospital Laboratory                      | 25 Highland Avenue<br>Newburyport, MA<br>01950<br>978-463-1096 |          | X               | X         | X         | 7/2/2003                     |
| Anne Arundel Medical Center                          | 2001 Medical Parkway<br>Annapolis, MD 21401<br>443-481-4211    |          | X               | X         | X         | 10/29/2001                   |
| Aurora Area Blood Bank                               | 1200 North Highland Ave<br>Aurora, IL 60506<br>630-892-7055    | X        |                 | X         | X         | 3/24/2006                    |
| Avera McKennan Hospital and University Health Center | 800 East 21st St<br>Sioux Falls, SD 57117<br>605-822-7110      | X        |                 | X         | X         | 3/18/2002                    |
| Belle Bonfils Memorial Blood Center                  | 717 Yosemite Cir<br>Denver, CO 80220<br>303-341-4000           | X        |                 | X         | X         | 5/7/2001 (d)<br>4/1/2003 (f) |
| Bergen Community Regional Blood Services             | 970 Linwood Ave West<br>Paramus, NJ 07653<br>201-444-03900     | X        |                 | X         | X         | 5/8/2006                     |
| Blood Assurance, Inc                                 | 700 East Third St<br>Chattanooga, TN 37403<br>423-756-0966     | X        |                 | X         | X         | 7/2/2002                     |
| Blood Bank of Delaware, Inc                          | 100 Hygenia Dr<br>Newark, DE 19713<br>302-737-8406             | X        |                 | X         | X         | 3/18/2002                    |

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|---|--|---|---|---|---|------------|
| The Blood Center of Central Iowa              | 431 East Locust St<br>Des Moines, IA 50309<br>515-288-0276                       | X |   | X | X | 1/13/2006  |
| The Blood Center of New Jersey                | 45 South Grove St<br>East Orange, NJ 07018<br>973-676-4700                       | X |   | X | X | 11/25/2002 |
| Blood Centers of the Pacific                  | 270 Masonic Ave<br>San Francisco, CA<br>94118<br>415-567-6400                    | X |   | X | X | 1/27/2003  |
| BloodCenter of Wisconsin, Inc                 | 638 North 18th St<br>Milwaukee, WI 53201<br>414-933-5000                         | X |   | X | X | 8/3/2005   |
| The Blood Connection                          | 515 Grove Rd<br>Greenville, SC 29605<br>864-255-5000                             | X |   | X | X | 1/30/2001  |
| Blood Systems, Inc                            | 6220 East Oak St<br>Scottsdale, AZ 85252<br>480-949-1412                         | X |   | X | X | 4/10/2002  |
| Central Illinois Community Blood Center       | 1134 South Seventh St<br>Springfield, IL 62703<br>217-753-1530                   | X |   | X | X | 10/10/2002 |
| Central Indiana Regional Blood Center         | 3450 North Meridian St<br>PO Box 88206<br>Indianapolis, IN 46208<br>317-916-5007 | X |   | X | X | 8/7/2003   |
| Central Kentucky Blood Center                 | 330 Waller Ave<br>Lexington, KY 40504<br>859-276-2534                            | X |   | X | X | 2/14/2001  |
| Coffee Memorial Blood Center                  | 1915 Coulter Dr<br>Amarillo, TX 79106<br>806-358-4563                            | X |   | X | X | 1/17/2001  |
| Community Blood Center of the Carolinas       | 4447 South Blvd<br>Charlotte, NC 28209<br>704-972-4700                           |   | X | X | X | 11/6/2006  |
| Community Blood Center of Greater Kansas City | 4040 Main St<br>Kansas City, MO 64111<br>816-968-4019                            | X |   | X | X | 10/8/2003  |
| Community Blood Center of the Ozarks          | 2230 S Glenstone<br>Springfield, MO 65804<br>417-227-5000                        | X |   | X | X | 12/2000    |
| Community Blood Council of New Jersey         | 1410 Parkside Ave<br>Trenton, NJ 08638<br>609-883-9750                           | X |   | X | X | 3/23/2005  |
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|--------------------------------------|---|---|---|---|---|------------|
| Cooley Dickinson Hospital Blood Bank | 30 Locust St<br>Northampton, MA<br>01060<br>413-582-2162  |   | X | X | X | 9/10/2001  |
| Emerson Hospital Blood Bank          | 133 Old Road to Nine Acre Corner<br>Concord, MA 01742<br>978-287-3360   |   | X | X | X | 5/7/2003   |
| Florida's Blood Centers              | 32 West Gore St<br>Orlando, FL 32806<br>407-849-6100  | X |   | X | X | 12/11/2000 |
| Florida Georgia Blood Alliance       | 536 West 10th Street<br>Jacksonville, FL 32206<br>904-353-8263  | X |   | X | X | 8/7/2003   |
| Gulf Coast Regional Blood Center     | 1400 La Concha<br>Houston, TX 77054<br>713-790-1200   | X |   | X | X | 12/24/2003 |
| HCSC-Blood Center                    | 1465 Valley Center Pky<br>Bethlehem, PA 18017<br>610-691-5850   | X |   | X | X | 3/29/2004  |
| Healthcare Provider Services, Inc    | 405 Promenade St<br>Providence, RI 12908<br>401-453-8599  | X |   | X | X | 10/10/2000 |
| Hinsdale Hospital Blood Bank         | 120 North Oak Street<br>Hinsdale, IL 60521<br>630-856-7845  |   | X | X | X | 3/22/2004  |
| Holyoke Hospital, Inc                | 575 Beech St<br>Holyoke, MA 01040<br>413-534-2500   | X |   | X | X | 7/22/2002  |
| Hoxworth Blood Center                | 3130 Highland Ave<br>Cincinnati, OH 45267<br>513-558-1200   | X |   | X | X | 6/7/2001   |
| Inland Northwest Blood Center        | 210 W Cataldo Ave<br>Spokane, WA 99204<br>509-624-0151  | X |   | X | X | 8/6/2001   |
| INOVA Heath Care Services            | 45745 Nokes Blvd<br>Sterling , VA 20166<br>571-434-3600   | X |   | X | X | 3/30/2006  |
| Kaiser Permanente                    | 9449 E. Imperial Hgwy<br>Downey, CA 90242<br>562-803-2800<br><br>5601 Desoto Ave<br>Woodland Hills, CA<br>91367 |   | X | X | X | 7/24/2000  |

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|   | 818-719-2647<br>4647 Zion Avenue<br>San Diego, CA 92129<br>619-528-5385<br><br>1515 N. Vermont<br>Los Angeles, CA 90027<br>323-783-6667 |   |   |   |   |            |
| Lenox Hill Hospital<br>Blood Bank           | 100 East 77th St<br>New York, NY 10021<br>212-434-2510  |   | X | X | X | 9/24/2001  |
| LifeShare Blood<br>Centers                  | 8910 Linwood Ave<br>Shreveport, LA 71106<br>318-222-7770  | X |   | X | X | 9/20/2006  |
| LifeSource Blood<br>Services                | 3636 Blvd of the Allies<br>Pittsburgh, PA 15213<br>412-209-7307   | X |   | X | X | 6/7/2002   |
| LifeSouth Community<br>Blood Centers        | 1221 NW 13th St<br>Gainesville, FL 32601<br>352-334-1000  | X |   | X | X | 12/18/2000 |
| Mary Greeley Medical<br>Center              | 1111 Duff Ave<br>Ames, IA 50010<br>515-239-2123   | X |   | X | X | 10/22/2001 |
| Medic, Inc                                  | 1601 Ailor Ave<br>Knoxville, TN 37921<br>865-524-3074   | X |   | X | X | 9/7/2000   |
| Memorial Blood<br>Centers of Minnesota      | 2304 Park Ave<br>Minneapolis, MN<br>55404<br>612-871-3300   | X |   | X | X | 9/24/2001  |
| Michigan Community<br>Blood Centers         | 1036 Fuller Ave, NE<br>P.O. Box 1704<br>Grand Rapids, MI<br>49501<br>616-774-2300   | X |   | X | X | 12/14/2005 |
| Mid-South Regional<br>Blood Center          | 1040 Madison Ave<br>Memphis, TN 38104<br>901-522-8585   | X |   | X | X | 2/3/2000   |
| Mississippi Valley<br>Regional Blood Center | 3425 E. Locust St<br>Davenport, IA 52803<br>563-359-5401  | X |   | X | X | 12/11/2001 |
| Montrose Memorial<br>Blood Bank             | 800 South 3rd<br>Montrose, CO 81401<br>970-240-7220   |   | X | X | X | 6/5/2003   |
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|--|---|---|---|---|---|------------|
| Mount Sinai Medical Center   | One Gustave L. Levy Pl<br>Blood Bank Box 1024<br>New York, NY 10029<br>212-241-8810 |   | X | X | X | 11/10/1999 |
| Warren Grant Magnuson Clinical Center (NIH)  | 9000 Rockville Pk, Bld 10,<br>Rm 1C711<br>Bethesda, MD 20892<br>301-496-4506        | X |   | X | X | 10/13/2000 |
| New York Blood Center  | 310 E 67th St<br>New York, NY 10021<br>212-570-3151                                 | X |   | X | X | 12/18/2000 |
| North Country Regional Blood Center  | 75 Beekman St<br>Plattsburgh, NY 12901<br>518-562-7404                              | X |   | X | X | 5/4/2006   |
| North Shore University Hospital Blood Bank at Manhasset                              | 300 Community Dr<br>Manhasset, NY 11030<br>516-562-0100                             |   | X | X | X | 7/10/06    |
| Northwest Florida Blood Center   | 2201 North 9th St<br>Pensacola, FL 32503<br>850-434-2535                            | X |   | X | X | 12/4/2001  |
| Ogden Medical Center, Inc  | 5475 South 500 East<br>Ogden, UT 84405<br>801-479-2281                              | X |   | X | X | 5/7/2001   |
| Oklahoma Blood Institute   | 1001 N. Lincoln Blvd<br>Oklahoma City, OK<br>73104<br>405-297-5700                  | X |   | X | X | 4/16/2004  |
| Our Lady of the Lake Hospital, Inc   | 5000 Hennessy Blvd<br>Baton Rouge, LA<br>70808<br>225-765-8843                      | X |   | X | X | 4/6/2001   |
| Our Lady of Lourdes Regional Medical Blood Center                                    | 611 St. Landry St<br>Lafayette, LA 70506<br>337-289-2176                            |   | X | X | X | 5/20/2002  |
| Path Lab Services Corporation (Adirondack, Seaway & Park Regional Blood Collections) | 4709 Route 9<br>Plattsburgh, NY 12901<br>518-562-5483                               |   | X | X | X | 1/13/2006  |
| Piedmont Blood Center, Inc.  | 175 Dunbar St<br>Spartanburg, SC 29306<br>864-582-6366                              | X |   | X | X | 8/31/2006  |
| Penrose - St. Francis Health Services Blood  | 2215 N. Cascade Avenue  |   | X | X | X | 1/7/2004   |

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|---|--|---|---|---|---|------------|
| Bank  | Colorado Springs, CO<br>80907<br>719-630-5160                                  |   |   |   |   |            |
| Puodre Valley Hospital<br>Blood Bank                        | 1024 South Lemay Ave<br>Ft. Collins, CO 80524<br>970-495-8700                  |   | X | X | X | 4/28/2005  |
| Regional Health<br>Resource Center                          | 1408 W. University<br>Ave<br>Urbana, IL 61801<br>217-367-2202                  | X |   | X | X | 12/5/2005  |
| Regional West Medical<br>Center                             | 4021 Avenue B<br>Scottsbluff, NE 69361<br>308-630-1400                         | X |   | X | X | 4/20/2005  |
| Rex Hospital, Inc   | 4420 Lake Boone Trail<br>Raleigh, NC 27607<br>919-784-4750                     | X |   | X | X | 6/23/2001  |
| St. John's Mercy<br>Medical Center                          | 615 S. New Ballas Rd<br>St. Louis, MO 63141<br>314-569-6398                    |   | X | X | X | 9/29/2003  |
| St. Luke's Hospital<br>Blood Bank                           | 1026 A Ave, NE<br>Cedar Rapids, IA<br>319-369-7315                             |   | X | X | X | 12/23/2002 |
| Sacramento Medical<br>Foundation                            | 1625 Stockton Blvd<br>Sacramento, CA 95816<br>916-456-1500                     | X |   | X | X | 12/24/2003 |
| Saints Memorial<br>Medical Center                           | One Hospital Dr<br>Lowell, MA 08152<br>978-458-1411                            |   | X | X | X | 3/18/2002  |
| Scott & White<br>Memorial Hospital                          | 2401 South 31st St<br>Temple, TX 76508<br>254-724-8868                         |   | X | X | X | 3/7/2005   |
| South Florida Blood<br>Banks, Inc                           | P.O. Box 078618<br>933 45th St<br>West Palm Beach, FL<br>33407<br>561-845-2323 | X |   | X | X | 1/17/2001  |
| Suncoast Communities<br>Blood Bank, Inc                     | 1760 Mound Street<br>Sarasota, FL 34236<br>941-954-1600                        | X |   | X | X | 2/2/2004   |
| University Hospital<br>Health Services Center<br>Blood Bank | State University of NY<br>Stony Brook, NY 11794<br>516-444-2626                |   | X | X | X | 5/13/2002  |
| University Medical<br>Center at Princeton                   | 253 Witherspoon Street<br>Princeton, NJ 08540<br>609-497-4353                  |   | X | X | X | 11/8/2005  |

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|--|---|---|--|---|---|------------|
| Veterans Administration Medical Center | 130 W Kingsbridge Rd<br>Bronx, NY 10468<br>718-741-4271             | X |  | X | X | 1/6/2000   |
| Virginia Blood Services                | 2201 Westwood Ave<br>Richmond, VA 23230<br>804-359-5100             | X |  | X | X | 10/21/2002 |
| Wellmont Health System                 | 130 West Ravine Rd<br>Kingsport, TN 37660<br>423-224-6740           | X |  | X | X | 5/24/2006  |
| Winter Haven Hospital                  | 460 First Street North<br>Winter Haven, FL<br>33881<br>863-297-1840 | X |  | X | X | 5/27/2003  |

Legend:

640.3(d) = 21 CFR 640.3(d) – blood withdrawn in order to promote the health of a donor otherwise qualified under the provisions of 640.3, shall not be used as a source of Whole Blood unless the container label conspicuously indicates the donor’s disease that necessitated withdrawal of blood.

640.3(f) = 21 CFR 640.3(f) – a person may serve as a source of Whole Blood more than once in 8 weeks only if at the time of donation the person is examined and certified by a physician to be in good health, as indicated in 640.3 (b).

Updated: November 28, 2006