



DEPARTMENT OF HEALTH AND HUMAN SERVICES

93682

August 14, 2002

**WARNING LETTER**  
**CHI-23-02**

Food and Drug Administration  
Chicago District Office  
Suite 1600  
650 W. Jackson Street  
Chicago, IL 60661  
Telephone: (312) 353-5863  
FAX: (312) 696-4195

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Dana E. Belisle, President  
Coral Blood Services, Inc.  
300 Professional Drive  
Scarborough, ME 04074

Dear Mr. Belisle:

An inspection of your unlicensed donor center located at 2300 Children's Plaza, Chicago, IL, was conducted on June 19, 20 & 26, 2002. The inspection revealed several significant deviations from the applicable standards and requirements of Parts 600-680, Title 21, Code of Federal Regulations (21 CFR). These deviations cause the blood products prepared at this location to be adulterated within the meaning of Section 501 (a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). At the conclusion of the inspection, a Form FDA 483, List of Inspectional Observations (FDA 483), was issued to and discussed with Penelope Compton, Director of Operations. The deviations noted on the FDA 483 include, but are not limited to, the following:

[1.] Failure to maintain a complete record from which unsuitable donors may be identified so that products from such individuals will not be distributed [21 CFR 606.160(e)]. For example, the donor of unit [REDACTED] tested ELA repeat reactive for HCV on 6/15-16/02. However, this donor's name was not included on the Donor Deferral Registry (DDR) which was updated on 6/20/02.

[2.] Failure to maintain complete and accurate donor records [21 CFR 606.160(b)]. The inspection found that your firm uses the standard operating procedure (SOP) entitled "COR-OPS-CLIN-030" in the donor registration and screening operation. This SOP is not adequate in that the procedure required to be followed should a donor indicate that they have donated or attempted to donate blood using a different name at this site or anywhere else, does not require that donor files be searched for a duplicate record following a name change. The procedure only requires that the DDR be reviewed to assure the donor was not deferred under his or her previous name. For example, the record for donor [REDACTED] indicates that the donor acknowledged a previous donation attempt under another name, but the record fails to indicate if the donor files were searched and/or merged.

[3.] Failure to maintain and follow adequate written SOPs for the collection, processing, compatibility testing, storage and distribution of blood and blood components [21 CFR 600.160(b)]. For example:

Written procedures do not address all operations for your firm. These procedures do not identify the records used, or the documentation maintained when look back operations are conducted. Also, approved procedures do not exist that identify the centrifuge spin speed or spin time used to prepare PRBC and FFP from Whole Blood.

Written procedures are not always followed. SOP "COR-QP-GEN-015" requires that Donor Registration and Screening Forms are to be reviewed before the product is released for distribution. For example, the records for units [REDACTED] and [REDACTED] indicate that the individual that performed the collection also conducted the review of the donor form. This same SOP requires that quality control records be reviewed within one month after completion. The FDA 483, item #3, provides examples in which this requirement of the SOP is not followed.

[4.] Failure to maintain records concurrently with the performance of each significant step in the collection, processing, compatibility testing, storage and distribution of each unit of blood and blood components so that all steps can be clearly traced [21 CFR 606.160(a)(1)]. For example, no documentation is maintained that indicates if, when and who performed look back operations, and no documentation is recorded of the time Whole Blood is centrifuged before separating PRBC and Plasma.

Neither this letter nor the Form FDA 483 is intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that this facility is in compliance with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to prevent the recurrence of similar violations. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the date by which corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

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Your reply should be directed to Compliance Officer George F. Bailey at the address indicated on the letterhead.

Sincerely,

\s\  
Arlyn Baumgarten  
District Director

cc: Ms. Penelope Compton, RN  
Director of Operations  
Coral Blood Services, Inc.  
2300 Children's Plaza  
Chicago, IL 60614