U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Immucor, Inc. 02-May-08

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Rockville MD 20857

MAY 0 2 2008

WARNING LETTER

OEWL-08-03

Express Mail

Gioacchino DeChirico
President and CEO
Immucor, Inc.
3130 Gateway Drive
P.O. Box 5625
Norcross, Georgia 30091

Dear Mr. DeChirico:

The Food and Drug Administration (FDA) conducted an inspection of Immucor, Inc., 3130 Gateway Drive, Norcross, Georgia, between January 8 and January 17, 2008 and determined that your firm manufactures serological reagents which are medical devices as defined under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) because they are intended for use in diagnosis of disease or other conditions. During the inspection, FDA investigators documented violations of Section 501(h) of the FD&C Act and deviations from applicable standards and requirements of Subchapter H, Part 820, Title 21, **Code of Federal Relations** (CFR). At the close of the inspection, our investigators issued a Form FDA 483, Inspectional Observations, which described a number of significant objectionable conditions relating to your facility's compliance with current good manufacturing practice (CGMP). Significant deviations in the manufacture of serological reagents observed during the inspection include, but are not limited to, the following:

1. You failed to establish and maintain procedures to control product that does not conform to specified requirements [21 CFR 820.90). For example:

a. Panocell-16 lot 17154 tested out of specifications for reactivity of the cells on May 16, 2006. The lot was released to inventory prior to completion of the investigation on May 23, 2006.

b. Panocell-10 lot 02722 was placed on hold alert after testing positive for microbial growth. The hold was removed, and the product was released for distribution on February 7, 2007, prior to completion of the investigation on April 9, 2007.

c. Ficin Panocell-10 lot 50664-E was placed on hold alert after testing positive for microbial growth . The hold was removed, and the product was released for distribution on January 17, 2007, prior to completion of the investigation on February 20, 2007.

d. Panoscreen lot 03739 was placed on hold alert after testing positive for microbial growth. The hold alert was removed, and the product was released for distribution on February 13, 2007, prior to completion of the investigation on February 21, 2007.

e. Panoscreen I & II, Lot 41500 was removed from inventory on November 10, 2006, due to complaints of clots and unexpected color from a related lot. Sales were made from this lot on November 14, 2006, and November 20, 2006, prior to your discarding the remaining inventory on November
30, 2006.

2. You failed to establish and maintain procedures for changes to a specification, method, process, or procedure [21 CFR 820.70(b)]. Your SOP GEN 118 entitled "Change Order" requires approval of change orders by **[redacted]** before implementation of a change. However, you initiated Change Order CO-06-014 for a process change in the manufacture of Capture-R-Screen/Ready-ID plates, lots ID069 and ID070. These lots were distributed prior to approval of the change by the quality unit on March 23, 2006.

3. You failed to establish and maintain complaint handling procedures to ensure that all complaint files are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting (MDR) [21 CFR 820.198 (a (3). For example, your SOP GEN.162, entitled, **[redacted]** requires MDR assessments in Risk Evaluation Summaries was not followed for the below-mentioned complaints:

a. Complaint relating to Panocell-16, lot 21210.

b. Complaints relating to Panoscreen II &111, lots 41500, 41507, 41508, 41489.

c. Complaint relating to Capture-R RID Extend II, lot DN017.

4. You failed to establish and maintain procedures for implementing corrective and preventive action, including requirements for investigating the cause of nonconforming product and identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems (21 CFR 820.100]. For example:

a. Your SOP GEN 106 entitled "Deviation Reporting" recommends a review of Customer Complaint Logs for similar deviations to determine product impact. However, investigations into deviations of Capture-R Ready Screen Plates, lots X155, X157, N097, N095, did not include a review of complaint files for similar deviations.

b. Your SOP BQA.101 entitled "Handling Microbiological Out of Specification Test Results" requires an investigation to be initiated as a result of a confirmed microbiological out-of-specification result. However, you did not investigate out-of-specfication microbial results for Panocell-l0, Lot 10832.

c. An investigation was not conducted for Panoscreen 1& II lot 41500, which was included in a recall initiated on November 29, 2006.

5. You failed to submit an MDR to FDA within 30 days of receiving information that reasonably suggests that your marketed device may have malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur [21 CFR 803.50(a) (2)J . Specifically, a complaint for an unexpected positive reaction with Immucor Anti-D, Series 4, lot 504694 was deemed MDR reportable on August 28, 2007. This report was not submitted to FDA until January 9, 2008.

We acknowledge receipt of your written responses dated February 5, 2007, February 7, 2007, and March 14, 2007, which address the inspectional

observations on the Form FDA 483 issued at the close of the inspection. We have reviewed your responses and accompanying documents. Corrective actions addressed in your responses may be referenced in your reply to this letter, as appropriate. However, your responses did not provide sufficient detail to fully assess the adequacy of your corrective actions. For example, your responses fail to discuss implementation of adequate quality assurance oversight to ensure prompt identification, correction, and follow up to problems associated with the manufacture of your products.

Neither this letter nor the list of inspectional observations (Form FDA 483) is meant to be an all-inclusive list of deficiencies that may exist at your facility. It is your responsibility as management to assure that your establishment is in compliance with the provisions of the FD&C Act, and applicable federal regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Please notify us in writing, within 15 working days of receipt of this letter, of any additional steps you have taken or will take to correct the noted violations and to prevent their recurrence. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, ORA/OE/Division of Compliance Management and Operations, HFC-210, 15800 Crabbs Branch Way, Rockville, MD 20855. If you have any questions regarding this letter, please contact Jacqueline Little, Ph.D., Team Biologics Compliance, Division of Compliance Management and Operations, at (240) 632-6863.

Sincerely,

/S/

David K. Elder
Director
Office of Enforcement

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