

of Source Plasma. This revocation notice affects only the Douglas Plasmalab, Douglas, AZ, facility and has no bearing on other establishment and product licenses issued to Plasmalab Donor Centers, Inc. In a letter to FDA dated March 28, 1994, the firm requested that the establishment and product licenses issued to its Douglas Plasmalab, Douglas, AZ, facility be revoked and thereby waived its opportunity for a hearing on the matter.

**DATES:** The revocation of the establishment license (U.S. License No. 1072-001) and product license became effective June 8, 1994.

**FOR FURTHER INFORMATION CONTACT:** Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** FDA has revoked the establishment license (U.S. License No. 1072-001) and the product license for the manufacture of Source Plasma issued to Plasmalab Donor Centers, Inc., doing business as Douglas Plasmalab at 11 J Ave., Douglas, AZ 85607.

FDA inspected Douglas Plasmalab at 11 J Ave., Douglas, AZ, from February 10, 1994, through March 9, 1994, following the report by the establishment of an error from the reinfusion of the wrong red blood cells to a donor undergoing plasmapheresis. The inspection revealed serious deviations from Federal regulations. FDA has determined that these deviations constitute a danger to health. These deficiencies included, but were not limited to, the following: (1) Failure to follow procedures designed to prevent the infusion of one donor's red blood cells into another donor (21 CFR 640.65(b)(3)); (2) failure to follow procedures designed to prevent contamination of red blood cells for reinfusion (21 CFR 640.64(e)); (3) failure to limit the frequency of Source Plasma donation to two times within a 7-day period (21 CFR 640.65(b)(5)); (4) failure to maintain accurate and concurrent records to document the performance of each significant step in the collection, processing, and storage of each unit of blood and blood components (21 CFR 606.160); and (5) failure to maintain adequate and complete standard operating procedures that are available to personnel in the areas where the procedures are performed for all steps in the collection, processing, storage, and distribution of Source Plasma (21 CFR 606.100(b)). The inspection indicated serious noncompliance with the donor protection standards which are intended

to assure a continuous and healthy donor population, as well as with standards designed to assure the continued safety, purity, potency, and quality of products manufactured.

In addition to the inspection, the agency conducted a concurrent investigation that involved interviews with individuals knowledgeable of the daily operations of Douglas Plasmalab. This investigation revealed that deviations routinely occurred in important areas of the plasmapheresis operation. These deviations included, but were not limited to, the following: Maintenance of inaccurate red blood cell reinfusion records, forced and unfiltered reinfusion of whole blood into donors whose donation of blood exceeded the legally allowable limit, and reinfusion of red blood cells which may have been contaminated through a break in the closed sterile system of collection.

FDA concluded that the serious nature of the deficiencies noted during the inspection and concurrent investigation at Douglas Plasmalab was a direct consequence of the establishment's disregard for the applicable regulations and standards in the license applications and constitutes a danger to public health warranting suspension pursuant to 21 CFR 601.6(a). In a letter to the firm dated March 17, 1994, FDA suspended and confirmed telephone notice of the suspension of the establishment license (U.S. License No. 1072-001) and the product license for Source Plasma. In a letter to FDA dated March 28, 1994, Plasmalab Donor Centers, Inc., voluntarily requested that its Douglas Plasmalab licenses be revoked and thereby waived its opportunity for a hearing. The agency granted the request by letter to the firm dated, June 8, 1994, which revoked the establishment license (U.S. License No. 1072-001) and the product license for the manufacture of Source Plasma.

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Biologics Evaluation and Research (21

CFR 5.68) the establishment license (U.S. License No. 1072-001) and the product license for the manufacture of Source Plasma issued to Plasmalab Donor Centers, Inc., Douglas, AZ, were revoked, effective June 8, 1994.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: April 8, 1995.

**Kathryn C. Zoon,**

*Director, Center for Biologics Evaluation and Research.*

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[Docket No. 94N-0298]

**Putnam County Blood Bank, Inc.;  
Revocation of U.S. License No. 1121**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 1121) and the product licenses issued to Putnam County Blood Bank, Inc., (PCBB) for the manufacture of Whole Blood, Red Blood Cells, Platelets, and Plasma. In a letter to FDA dated April 29, 1994, the firm requested that its establishment and product licenses be revoked and thereby waived its opportunity for a hearing on the matter.

**DATES:** The revocation of the establishment license (U.S. License No. 1121) and product licenses became effective June 3, 1994.

**FOR FURTHER INFORMATION CONTACT:** Timothy W. Beth, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

**SUPPLEMENTARY INFORMATION:** FDA conducted an inspection of PCBB, 2919 Kennedy St., Palatka, FL 32077, from September 1, 1992, through October 6, 1992. The inspection revealed serious deviations from Federal regulations. FDA determined these deviations to constitute a danger to public health. These deficiencies included, but were not limited to, the following: (1) Failure to establish scientifically sound and appropriate specifications, standards, and test procedures to assure that blood and blood components are safe, pure, potent, and effective (21 CFR 606.140(a) and 610.45(c)), and (2) failure to institute systems capable of precluding release of unsuitable blood and blood components (21 CFR 640.3(b) and (c) and 606.160(b)(1)(ii) and (e)).

Because of these serious deviations, FDA concluded that the management at PCBB did not adequately demonstrate the ability to operate the establishment in a manner that assured compliance with Federal regulations or accepted standard operating procedures, or to ensure that personnel were adequately trained and supervised and had a thorough understanding of the procedures that they performed as required by 21 CFR 600.10(a) and (b) and 606.20(a) and (b). These conditions at PCBB were considered to constitute a danger to public health warranting license suspension pursuant to 21 CFR 601.5(b) and 601.6(a). FDA accordingly suspended the firm's licenses by letter dated November 6, 1992.

In addition to the suspension of establishment and product licenses, and in order to preclude the distribution of violative units, and to address those questionable units already in distribution channels, FDA requested that PCBB immediately and concurrently perform the following: (1) Review test records for antibody to the human immunodeficiency virus (Type I), and then identify and defer all donors who may have been misinterpreted as suitable due to improper donor reentry procedures; (2) develop and implement a plan to identify and defer all donors who, during the medical history interview, have provided information which may deem such donors as ineligible, and (3) identify and recall all units collected from such donors, and notify all consignees of transfusable and nontransfusible blood and blood components of the test/medical history of the units. In a letter to the firm dated March 9, 1994, FDA concluded that the recall was complete.

In a letter to FDA dated April 29, 1994, PCBB voluntarily requested that its licenses be revoked and thereby waived its opportunity for a hearing. The agency granted the request in a letter dated June 3, 1994, which revoked the establishment and product licenses.

FDA has placed copies of the letters relevant to the license revocation on file under the docket number found in brackets in the heading of this document with the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Accordingly, under 21 CFR 601.5, section 351 of the Public Health Service Act (42 U.S.C. 262), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and

redelegated to the Director, Center for Biologics Evaluation and Research (21 CFR 5.68), the establishment license (U.S. License No. 1121) and the product licenses for the manufacture of Whole Blood, Red Blood Cells, Platelets, and Plasma issued to Putnam County Blood Bank, Inc., Palatka, FL, were revoked, effective June 3, 1994.

This notice is issued and published under 21 CFR 601.8 and the redelegation at 21 CFR 5.67.

Dated: April 11, 1995.

**Kathryn C. Zoon,**

*Director, Center for Biologics Evaluation and Research.*

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[Docket No. 95N-0090]

**Dietary Supplements: Notice of Withdrawal of Regulatory Guidance**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that it has withdrawn a number of import alerts, import bulletins, and compliance policy guides involving dietary supplements. FDA has taken these actions to conform its regulatory guidance to the changes made to the Federal Food, Drug, and Cosmetic Act (the act) by the Dietary Supplement Health and Education Act (DSHEA).

**FOR FURTHER INFORMATION CONTACT:** Loretta A. Branch Carey, Center for Food Safety and Applied Nutrition (HFS-456), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-205-5372.

**SUPPLEMENTARY INFORMATION:** On October 25, 1994, the President signed into law the DSHEA (Pub. L. 103-417). Among the most significant changes in the act made by the DSHEA is the addition of section 201(s)(6) (21 U.S.C. 321(s)(6)), which exempts dietary ingredients of dietary supplements from coverage under the food additive provisions of the act (section 3(b) of the DSHEA). As a result of this change, such ingredients are no longer subject to a premarket safety review.

In response to this change, FDA has reviewed the regulatory guidance that it issues to its field offices to conform that guidance to the change. As a result of this review, FDA has found that it is appropriate to withdraw the following import alerts, import bulletins, and compliance policy guides because they are no longer consistent with the act.

**A. Compliance Policy Guides**

1. CPG 7117.04, entitled "Botanical Products for use as Food"
2. CPG 7118.01, entitled "Dietary Supplements-Misbranding Nutritionally Insignificant Ingredients"

**B. Import Alerts**

1. 24-14 Products containing Bracken
2. 26-02 Flaxseed/Linseed Oil
3. 54-03 Carnitine
4. 54-05 Ultra Bios 2000 Food Supplement
5. 66-02 Ginseng
6. 66-04 Oil of Evening Primrose

**C. Import Bulletins**

1. 31-B01 Selfheal Flower, *Prunella Vulgaris*
2. 54-B06 Tricosanthis
3. 66-B62 Ephedra

The Agency continues to review and revise the remaining related import alerts, bulletins, and compliance policy guides, in order to comply with DSHEA.

FDA notes that it does not usually give notice in the **Federal Register** of its issuance or withdrawal of import alerts or bulletins. It is doing so in this instance, however, because of the ongoing congressional interest in FDA's implementation of the DSHEA. FDA advises that issuing this notice does not mark any type of change in the agency's usual procedures for issuing or withdrawing these alerts or bulletins.

In response to the DSHEA, FDA has also reassessed its general enforcement priorities with respect to dietary supplements. FDA advises that in enforcing the act with respect to these products, its primary focus is likely to be, as it always has been, on safety concerns. The agency advises, however, that its regulatory priorities are subject to adjustment in response to changing circumstances. For example, the labeling of dietary supplements will likely be given a higher priority by the agency after December 31, 1996, when compliance with FDA's nutrition labeling and nutrient content claim regulations for dietary supplements is to begin.

Dated: April 13, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95-9702 Filed 4-18-95; 8:45 am]

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[Docket No. 84N-0102]

**Cumulative List of Orphan-Drug and Biological Designations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.