

FDA conducted an inspection and concurrent investigation of BSI from March 23 through April 14, 1993. The inspection and concurrent inspection revealed serious deviations from the standards established in the applicable Federal regulations and approved license.

The concurrent investigation revealed significant deficiencies that occurred routinely in quality control recordkeeping, as well as in personnel training and supervision. BSI employees, with the knowledge of management, falsified blood storage temperature records whenever the temperature was outside the range specified in written procedures. BSI employees also routinely discarded donor registration forms of temporarily deferred donors because the staff would receive negative performance evaluations if a high number of donors were deferred.

During the inspection, FDA observed deviations that included, but were not limited to, the following: (1) Failure to determine donor suitability, in that BSI accepted donations from individuals who reported disqualifying information (21 CFR 640.3(b)); (2) failure to adequately prepare the donor's phlebotomy site by a method that gives maximum assurance of sterility, in that the site was sometimes repalpated after the arm scrub was performed, and the arm scrubs were performed for less than the 30 seconds required by BSI's standard operating procedures (21 CFR 640.4(f)); and (3) failure to assure that the personnel responsible for the collection of blood on mobile drives were adequate in number, in that it was observed that donors were rushed through medical history questions, were not provided with adequate privacy during medical history interviews, and were only allowed 1 to 2 minutes of recovery time following blood donation (21 CFR 606.20(b)).

The inspection observations and the concurrent investigation showed that BSI knowingly falsified blood storage records. Consequently, FDA determined that BSI willfully failed to comply with the standards established in the approved license and in the applicable regulations. In accordance with that determination, FDA initiated proceedings under 21 CFR 601.5(b) for license revocation without providing BSI with an opportunity to achieve or demonstrate compliance.

In a letter to BSI dated June 1, 1993, FDA delineated the observations listed above and announced its intent to offer an opportunity for a hearing on FDA's proposal to revoke U.S. License 0183-020 issued to BSI. In a letter to FDA

dated June 28, 1993, BSI requested voluntary revocation of its license and waived its opportunity for a hearing under 21 CFR 601.5(a). In a letter dated July 23, 1993, FDA acknowledged voluntary revocation of the establishment license (U.S. License No. 0183-020) and the aforementioned product licenses of BSI at the Texarkana, TX, location.

FDA has placed copies of documents relevant to the license revocation on file under the docket number found in brackets in the heading of this notice 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. 0183-020) and product licenses for Whole Blood (ACD, CPD, CPDA-1), Red Blood Cells, Red Blood Cells Leukocytes Removed, Plasma, Fresh Frozen Plasma, Cryoprecipitated AHF, Platelets, Platelets Pheresis, and Source Leukocytes issued to BSI at the Texarkana, TX, location were revoked, effective July 23, 1993.

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. 88G-0388]

Fuji Oil Co., Ltd.; Filing of Petition for Affirmation of GRAS Status; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a petition (GRASP 8G0348) filed by Fuji Oil Co., Ltd., proposing to affirm that cocoa butter substitutes from safflower oil and sunflower oil are generally recognized as safe (GRAS) for use as direct human

food ingredients. This amendment is intended to clarify that the sunflower and safflower oils used in the manufacture of the petitioned cocoa butter substitute are the high-oleic rather than the typical high-linoleic varieties.

DATES: Comments by July 12, 1995.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3097.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of January 26, 1989 (54 FR 3853), FDA announced that Fuji Oil Co., Ltd., 6-1, Hachiman-cho, Minami-ku, Osaka 542 Japan, had filed a petition (GRASP 8G0348) proposing to affirm that cocoa butter substitutes from safflower oil and sunflower oil are GRAS for use as direct human food ingredients. The agency recognizes that the terms "safflower oil" and "sunflower oil" normally refer to the traditional high-linoleic varieties. However, the agency has determined that the proposed starting materials for the manufacture of the petitioned cocoa butter substitutes are the high-oleic rather than the typical high-linoleic safflower or sunflower oils. Therefore, the agency is amending the filing notice to make this distinction clear.

Interested persons may, on or before July 12, 1995, submit to the Dockets Management Branch (address above) written comments with respect to the above mentioned change only. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comment are to be identified with the docket number found in brackets in the heading of this document. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 19, 1995.

Alan M. Rulis,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

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