

Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. See the

SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components" dated December 2003. The guidance recognizes that the circular dated July 2002 meets the labeling requirements in § 606.122 (21 CFR 606.122) and is acceptable for use by manufacturers of blood and blood components intended for transfusion that are subject to U.S. statutes and regulations. The circular was prepared jointly by the American Association of Blood Banks, America's Blood Centers, and the American National Red Cross. A copy of the circular is included as an attachment in

the guidance document. The guidance announced in this notice finalizes the draft guidance of the same title, dated October 2002 (67 FR 64402, October 18, 2002).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance document represents the agency's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance and the circular at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>. The circular may also be obtained at <http://www.aabb.org>. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this

document publishes in the **Federal Register**.)

Dated: December 1, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: November 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of November 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

OFFICE OF INVESTIGATION, OFFICE OF INSPECTOR GENERAL—DHHS, CASE INVESTIGATION MANAGEMENT SYSTEM

[For Press Release From 11/01/2003—11/30/2003]

Subject name	Address	Effective date
PROGRAM-RELATED CONVICTIONS:		
ALLEN, KENNETH	JUNCTION, UT	12/18/2003
ALMO, JENNIFER	LEXINGTON, MS	12/18/2003
ALVARENGA, MARIA	LOS ANGELES, CA	12/18/2003
ARRIOLA, ALICIA	BELL GARDENS, CA	12/18/2003
ATTIKIAN, ARMEN	VAN NUYS, CA	12/18/2003
BARMORE, BURTON	GOLDSBORO, NC	12/18/2003
BELL, DIANE	HOUSTON, TX	12/18/2003
BIRMINGHAM REHABILITATION & PHYSICAL THERAPY CTR, INC	BLOOMFIELD, MI	12/18/2003
BRADLEE PHARMACY, INC	LAS VEGAS, NV	12/18/2003
BURDEN, MARGARET	VIDALIA, LA	12/18/2003
CORE, NICKLAUS	CHANDLER, AZ	12/18/2003
EMMONS, ROSLYN	WASHINGTON, VT	12/18/2003
GAZO, MARIA	NORWALK, CA	12/18/2003
GOFF, ELBERT	LOUISVILLE, KY	12/18/2003
GRAHAM, CARLIN	TALLADEGA, AL	12/18/2003
HEWETT, NANCY	EIGHT MILE, AL	12/18/2003
ISMAIL, MOHAMED	PARSIPPANY, NJ	12/18/2003