TABLE 1—Continued

Metropolitan Area	Conference Address	FDA Contact Person
Phoenix, AZ	United Artists Christown Mall, 1546 West Montebello, Phoenix, AZ	Gil Meza, 602–379–4595
Portland, OR	Westgate 5, 3950 SW. Cedar Hills Blvd., Beaverton, OR	Alan Bennett, 503–671–9332
Raleigh, NC	Mission Valley Cinemas, 2109 Advent Ferry Rd., Raleigh, NC	JoAnn Pittman, 404–347–4001, ext. 5340
Saint Louis, MO	Westport Cinema, 910 Westport Plaza St., Louis, MO	Mary-Margaret Richardson, 314–645–1167, ext. 123
Salt Lake City, UT	Broadway Center Cinema, 111 East Broadway, Salt Lake City, UT	Virlie Walker, 303–236–3018
San Diego, CA	United Artists Horton Plaza, 475 Horton Plaza, San Diego, CA	Rosario Vior, 714–798–7607
San Francisco, CA	UA Emery Bay 10, 6330 Christie Ave., Emeryville, CA	Janet McDonald, 510–337–6845
San Juan, PR	United Artists Cinema, 150 Laguna Garden Shopping Ctr., San Juan, PR	Ruth Marcano, 787–729–6842

Dated: January 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1719 Filed 1–21–97; 3:06 pm]

BILLING CODE 4160–01–F

[Docket No. 96N–0061]

Gary D. Mays; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Mr. Gary D. Mays, 5304 John Thomas Dr. NE., Albuquerque, NM 87111, for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biological product license application or an establishment license application. FDA bases this order on a finding that Mr. Mays was convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the act while he was employed as responsible head of El Paseo Plasma, Inc., located at 1595 El Paseo, Las Cruces, NM. After being given notice of his proposed debarment and opportunity to request a hearing, Mr. Mays has failed to request a hearing. Therefore, Mr. Mays has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: January 24, 1997

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gloria Hicks, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1989, the United States District Court for the District of New Mexico accepted a plea of guilty and entered judgment against Mr. Gary D. Mays for one count of a conspiracy to provide false statements in a matter within the jurisdiction of a Federal agency, a Federal felony offense under 18 U.S.C. 371. The basis for this conviction was Mr. Mays' act of falsification of whole blood logs, donor record files, quality control logs, destruction logs, records concerning the infusion of red blood cells to the wrong donor, and concealing and covering up by false statements at least two incidents of misconnecting for infusion, but not infusing, one donor with the red blood cells of another donor.

In order for FDA to regulate the blood plasma supply adequately and effectively, FDA requires that blood plasma facilities maintain accurate and complete records containing information regarding whole blood logs, donor record files, quality control logs, and destruction logs. Such records are crucial for FDA to assure that plasma products are safe, pure, and potent, and that the health of donors is protected in order to assure a continued healthy donor population. Because of Mr. Mays' omissions and falsifications in such records, FDA was prevented from obtaining accurate and complete information necessary to regulate the human blood plasma supply, and, therefore, FDA's process for the regulation of drug products was undermined.

As a result of his conviction, FDA delivered a letter, dated December 5, 1994, to Mr. Mays which provided notice of FDA's proposal to debar him for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biological product license application or an establishment license application, and offered him an opportunity for a hearing on the proposal in accordance with 21 U.S.C. 335a and 21 CFR part 12. FDA based the proposal on its finding under section 306(b)(2)(B)(i)(II) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II)) that Mr. Mays was convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Mays did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Deputy Commissioner for Operations, under section 306(b) of the act, and under authority delegated

by 21 CFR 5.20, finds that Mr. Gary D. Mays has been convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the act and that the type of conduct which served as the basis for his conviction undermines the process for the regulation of drugs (21 U.S.C. 335a(b)(2)(B)(i)(II)).

As a result of the foregoing finding, and due to the nature and seriousness of his offense, Mr. Gary D. Mays is debarred for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application under sections 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or biological product license application or establishment license application under section 351 of the Public Health Service Act (42 U.S.C. 262), effective January 24, 1997 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii)). In addition, FDA will not accept or review any abbreviated new drug application or abbreviated antibiotic drug application from Mr. Mays during his period of debarment (21 U.S.C. 335a(c)(1)(B)). Any person with an approved or pending drug product application including, but not limited to, a biological product license application or an establishment license application, who knowingly uses the services of Mr. Mays in any capacity during his period of debarment will be subject to civil money penalties (21 U.S.C. 335b(a)(6)). If Mr. Mays during his period of debarment provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a biological product license application or an establishment license application, he will be subject to civil money penalties (21 U.S.C. 335b(a)(7)).

Any application by Mr. Mays for termination of debarment under section 306(d)(4) of the act should be identified with the docket number found in brackets in the heading of this notice and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 1997.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 97–1784 Filed 1–23–97; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–253M]

Cigarettes and Smokeless Tobacco; Notice of Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will hold 10 public meetings to promote understanding of, and encourage proper compliance with, FDA's final regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. The meetings will focus on those provisions of the final rule that will take effect February 28, 1997 (see the ''SUPPLEMENTARY INFORMATION'' section in this document). FDA officials will be present at these meetings to explain the new regulations, and will be available to answer questions.

DATES: See Table 1 in the ''SUPPLEMENTARY INFORMATION'' section of this document.

ADDRESSES: See Table 1 in the ''SUPPLEMENTARY INFORMATION'' section of this document.

FOR FURTHER INFORMATION CONTACT: See Table 1 in the ''SUPPLEMENTARY INFORMATION'' section of this document.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 28, 1996 (61 FR 44396), FDA published a final rule to restrict the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents. These regulations address the serious public health problem caused by cigarettes and smokeless tobacco products. The goal of the final rule is to reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and to decrease significantly the amount of positive imagery that makes these products so appealing to children.

The provisions in the final rule have different effective dates. Starting February 28, 1997, Federal regulations will prohibit retailers from selling cigarettes, cigarette tobacco, or smokeless tobacco to any person under the age of 18, and will require retailers to check the photographic identification of every person under the age of 27 who wishes to purchase such a product to verify that the purchaser is at least 18 years old. Under the current schedule, starting August 28, 1997, the remaining provisions of the rule will become effective, except for the sponsorship provision, which will become effective on August 28, 1998.

The meetings will be held at the addresses and on the dates listed in Table 1 and are scheduled to last 1 hour.

There is no charge to attend these meetings. Advance registration is requested because seating is limited. The deadline for registering is 1 week before each meeting. Registration will be accepted so long as space is available. Late registration will be accepted only if space is available. Persons interested in attending should mail or telephone their name, organization, address, and telephone number to FDA's contact persons listed in Table 1 for each meeting location.

TABLE 1

Meeting Address	Date and Local Time	FDA Contact Person
BALTIMORE: Baltimore Sheraton Inner Harbor Hotel, 300 South Charles St., Baltimore, MD.	February 11, 1997, Tuesday 11 a.m. to 12 m.	Leonard Genova, 900 Madison Ave., Baltimore, MD, 21201, 410–962–3731
BOSTON: Park Plaza Hotel, Plaza Ballroom, 64 Arlington St., Boston, MA.	February 11, 1997, Tuesday 10 a.m. to 11 a.m.	Paula Fairfield, One Montvale Ave., Stoneham, MA, 02810, 617–279–1675, ext. 184
DETROIT: Harper Hospital, 3990 John Rd., Detroit, MI.	February 12, 1997, Wednesday 1:30 p.m. to 2:30 p.m.	Evelyn DeNike, 1560 East Jefferson, Detroit, MI, 48207, 313–226–6158