

many national and international guidelines and statements to make recommendations about possible ways to enhance international collaborative research.

**Providing Comments to the Draft Report**

You may provide written comments electronically or through mail or fax. Electronic submissions (by email or by website) are preferred as they will be processed more efficiently. The following are addresses for submitting comments: e-mail: nbac@od.nih.gov, NBAC website: www.bioethics.gov, mail: 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, fax: (301) 480-6900.

If your comments are not postmarked by November 13, 2000, we can not guarantee they will be given full consideration.

To Receive a Copy of this Draft Report  
 Contact: National Bioethics Advisory Commission, 6705 Rockledge Drive, Suite 700, Bethesda, Maryland 20892-7979, telephone (301) 402-4242, fax number (301) 480-6900, or visit the website at www.bioethics.gov.

**SUPPLEMENTARY INFORMATION:** The President established the National Bioethics Advisory Commission (NBAC) on October 3, 1995 by Executive Order 12975 as amended. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council, its Chair, the President, and other entities on bioethical issues arising from the research on human biology and behavior, and from the applications of that research.

Dated: September 25, 2000.  
**Eric M. Meslin,**  
*Executive Director, National Bioethics Advisory Commission.*  
 [FR Doc. 00-25018 Filed 9-28-00; 8:45 am]  
**BILLING CODE 4167-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Provision of Services in Interstate Child Support.

OMB No.: 0970-0085.

*Description:* Pub. L. 104-193, The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996 amended 42 U.S.C. 666 to require State Child Support Enforcement (CSE) programs to enact the Uniform Interstate Family Support Act (UIFSA) into State law by January 1, 1998. To ensure standardization among States, section 311(b) of UIFSA requires the States to use standard interstate forms, as mandated by Federal law. 45 CFR 303.7 requires CSE programs to transmit child support case information on standard interstate forms when referring cases to other States for processing. The forms, which promote uniformity and standardization, are expiring and we are taking the opportunity to make minor revisions to them, to among other things, reflect that UIFSA is now the law for all 54 CSE programs.

*Respondents:* States.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Transmittal #1 .....	54	10,861.20	.42	246,332.02
Transmittal #2 .....	54	2,715.30	.08	11,730.01
Transmittal #3 .....	54	543.05	.17	4,985
Uniform Petition .....	54	5,430.60	.12	35,190.29
General Testimony .....	54	6,516.72	.33	116,127.95
Affidavit/Paternity .....	54	2,715.30	.25	36,656.55
Locate Data Sheet .....	54	375	.08	1,620
Notice/Control Order .....	54	8,145.75	.17	74,777.98
Registration Statement .....	54	7,168.39	.17	65,805.82

*Estimated Total Annual Burden Hours:* 593,226.

*Additional Information:* Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance officer.

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed

information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: September 21, 2000.  
**Bob Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 00-24977 Filed 9-28-00; 8:45 am]  
**BILLING CODE 4184-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 94N-0371]

**Rami Elsharaiha; 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) permanently debarring Mr. Rami Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases

this order on a finding that Mr. Elsharaiha was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Elsharaiha failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** September 29, 2000.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5640.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On March 4, 1994, the U.S. District Court for the District of Maryland entered judgment against Mr. Elsharaiha for one count of making false declarations before a grand jury, a Federal felony offense under 18 U.S.C. 1623.

As a result of this conviction, FDA published in the **Federal Register** of January 19, 1999 (64 FR 2905), a notice proposing to permanently debar Mr. Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application, and offering him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Elsharaiha was provided 30 days to file objections and request a hearing. Mr. Elsharaiha 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 Director of the Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Rami Elsharaiha has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Rami Elsharaiha is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application

under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective September 29, 2000, (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Elsharaiha, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Elsharaiha, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Elsharaiha during his period of debarment.

Any application by Mr. Elsharaiha for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0371 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: September 11, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 00-25087 Filed 9-28-00; 8:45 am]

**BILLING CODE 4160-01-F**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-2674]

**Jay Marcus; 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. Jay Marcus for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus failed to request a hearing and, therefore, has waived his

opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** September 29, 2000.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Christine F. Rogers, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On October 21, 1994, the U.S. District Court for the District of Maryland accepted Mr. Marcus' plea of guilty to one count of conspiracy to defraud the United States under 18 U.S.C. 371 and sentenced Mr. Marcus for the crime.

As a result of this conviction, FDA published in the **Federal Register** of October 15, 1999 (64 FR 55944), a proposal to debar Mr. Marcus for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Marcus an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i) of the act (21 U.S.C. 355a(b)(2)(B)(i)), that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus was provided 30 days to file objections and request a hearing. Mr. Marcus 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 Director, Center for Drug Evaluation and Research, under section 306(b)(2)(B)(i) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Jay Marcus has been convicted of a felony under Federal law for conspiracy to defraud the United States.

As a result of the foregoing finding, Mr. Jay Marcus is debarred for a period of 5 years from providing services in any capacity to a person with 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 under section 351 of the Public Health Service Act (42 U.S.C. 262), effective September 29, 2000 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or