ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Protection and Advocacy (P&A) Voting Access Annual Report	55	1	16	880

Estimated Total Annual Burden Hours: 1,980.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2012–3986 Filed 2–21–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Understanding the Dynamics of Disconnection from Employment and Assistance.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the ''Understanding the Dynamics of Disconnection from Employment and Assistance'' research project. The purpose of this study is to improve understanding of low-income individuals and families who are disconnected from employment and from public assistance and particularly those not receiving cash assistance through the Temporary Assistance for Needy Families (TANF) program. ACF is proposing to use a discussion guide to collect qualitative information from respondents who are low-income and disconnected from employment and public assistance. The guide will be used to interview respondents in order to learn about their experiences with disconnection. Topics will include recent employment and reasons for not working; use of public benefit programs and reasons for using or not using specific benefits; their financial circumstances and material well-being including the stability and sources of income, housing and living arrangements; their coping strategies for addressing their circumstances; and their views on potential pathways out of disconnectedness.

Respondents: Individuals who are low-income, disconnected from employment and public assistance, and living in low-income areas targeted by the study.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide	72	1	1.5	108

Estimated Total Annual Burden Hours: 108.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: February 14, 2012.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–3945 Filed 2–21–12; 8:45 am]

BILLING CODE 4184–09–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0585]

Stephen L. Marks: 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 FD&C Act) permanently debarring Stephen L. Marks from providing services in any capacity to a person that has an approved or pending drug product application. We base this order on a finding that Mr. Marks was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Mr. Marks was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Mr. Marks failed to respond. Mr. Marks' failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective February 22, 2012.

ADDRESSES: Submit applications for special termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., rm. 4144, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On June 23, 2011, the U.S. District Court for the Middle District of Pennsylvania entered judgment against Mr. Marks for: Conspiracy to distribute misbranded controlled substances in violation of 21 U.S.C. 846; causing the misbranding of a drug product by dispensing a prescription drug product without a valid prescription in violation of 21 U.S.C. 331(k); and aiding and abetting in a monetary transaction in criminally derived property of a value greater than $10,000 in violation of 18 U.S.C. 1957 and 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the regulation of a drug product. The factual basis for this conviction is as follows: Mr. Marks was a pharmacist licensed to practice as a pharmacist in Pennsylvania. Mr. Marks managed and operated Pharmacy Services, Inc. (PSI, Inc.), a pharmacy registered with the Drug Enforcement Administration. This registration permitted Mr. Marks to fill prescriptions for and dispense certain controlled substances. From on or about June 2004, through January 2006, Mr. Marks and other employees of PSI, Inc. dispensed and distributed controlled substances for businesses that used telemarketers and Web sites to market, sell, and distribute controlled substances, including pain medications and stimulants, to individuals throughout the United States. From on or about June 2004, through on or about January 2006, in the Middle District of Pennsylvania, with intent to defraud and mislead, Mr. Marks did an act that caused drugs to be misbranded after they moved in interstate commerce and while they were held for sale, in that he dispensed the prescription drugs hydrocodone and Didrex, both of which are Schedule III controlled substances, without a valid prescription of a practitioner licensed by law to administer such drugs.

As a result of his convictions, on September 30, 2011, FDA sent Mr. Marks a notice by certified mail proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Marks was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Marks an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. The proposal was received on October 6, 2011. Mr. Marks failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and has waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director (Staff Manual Guide 1410.35), finds that Stephen L. Marks has been convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Marks 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 FD&C 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 (see **DATES**) (see sections 306(c)(1)(B), (c)(2)(A)(ii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Marks, in any capacity during Mr. Marks' debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Marks provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7)). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Marks during his period of debarment (section 306(c)(1)(A) of the FD&C Act (21 U.S.C. 335a(c)(1)(A))).

Any application by Mr. Marks for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) should be identified with Docket No. FDA–2011–N–0585 and sent to the Division of Dockets Management (see **ADDRESSES**). 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 7, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–4064 Filed 2–21–12; 8:45 am]

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