FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 21, 2011.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Ralph C. Stayer, Naples, Florida, individually, and Ralph C. Stayer together with Shelly A. Stayer, Naples, Florida, the RFS 2010 Irrevocable Trust F/B/O Ralph C. Stayer, the Shelly A. Stayer 2010 Childrens Trust, Michael G. Kuechler and Mary A. Kuechler, Fond du Lac, Wisconsin, Michael G. Kuechler and Ralph C. Stayer as trustees of the RFS 2010 Irrevocable Trust F/B/O Ralph C. Stayer, and Michael G. Kuechler and Mary A. Kuechler as trustees of the Shelly A. Stayer 2010 Childrens Trust, as a group acting in concert,* to acquire 10 percent or more of the voting shares of Hometown Bancorp, Ltd., Fond du Lac, Wisconsin, and thereby indirectly acquire control of Hometown Bank, Fond du Lac, Wisconsin.

Board of Governors of the Federal Reserve System, April 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child and Family Services Plan (CFSP), Annual Progress and Servicers Review (ASPR), and Annual Budget Expenses Request and Estimated Expenditures (CFS–101).

OMB No.: 0980–0047.

Description: Under title IV–B, subparts 1 and 2, of the Social Security Act (the Act), States, Territories, and Tribes are required to submit a Child and Family Services Plan (CFSP). The CFSP lays the groundwork for a system of coordinated, integrated, and culturally relevant family services for the subsequent five years (45 CFR 1357.15(a)(1)). The CFSP outlines initiatives and activities the State, Tribe or territory will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families. By June 30 of each year, States, Territories, and Tribes are also required to submit an Annual Progress and Services Report (APSR) and a financial report called the CFS–101. The APSR is a Yearly report that discusses progress made by a State, Territory or Tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains new and updated information about service needs and organizational capacities throughout the five-year plan period. The CFS–101 has three parts. Part I is an annual budget request for the upcoming fiscal year. Part II includes a summary of planned expenditures by program area for the upcoming fiscal year, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by program area, and the geographic areas served for the last complete fiscal year.

The Child and Family Services Improvement Act of 2006 amended Title IV–B, subparts 1 and 2, adding a number of requirements that affect reporting through the APSR and the CFS–101. Of particular note, the law added a provision requiring States (including Puerto Rico and the District of Columbia) to report data on caseworker visits (section 424(e) of the Act). States must provide annual data on (1) the percentage of children in foster care under the responsibility of the State who were visited on a monthly basis by the caseworker handling the case of the child; and (2) the percentage of the visits that occurred in the residence of the child. In addition, by June 30, 2008, States must set target percentages and establish strategies to meet the goal that; by October 1, 2011; at least 90 percent of the children in foster care are visited by their caseworkers on a monthly basis and that the majority of these visits occur in the residence of the child (section 424(e)(2)(A) of the Act).

Respondents: States, Territories, and Tribes must complete the CFSP, APSR, and CFS–101. Tribes and territories are exempted from the monthly caseworker visits reporting requirement of the APSR. There are approximately 180 Tribal entities that are eligible for IV–B funding. There are 52 States (including Puerto Rico and the District of Columbia) that must complete the CFSP, APSR, and CFS–101. There are a total of 232 possible respondents.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ASPR	232	1	76.58	17,766.56
CFSP	232	1	120.25	27,898
CFS–101, Parts I, II, and III	232	1	4.38	1,016.16
Caseworker Visits	52	1	99.33	5,165.16

Estimated Total Annual Burden Hours: 51,845.88.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. E-mail 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, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–8164 Filed 4–5–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0450]

Maria Carmen Palazzo: 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 Maria Carmen Palazzo, M.D. 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 Dr. Palazzo was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act. Dr. Palazzo was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Palazzo failed to respond. Dr. Palazzo's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 6, 2011.

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 (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) and (B) of the FD&C Act (21 U.S.C. 335a(a)(2)(A) and (B)) require debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of any drug product under the FD&C Act.

On August 19, 2010, the United States District Court for the Eastern District of Louisiana accepted Dr. Palazzo's plea of guilty, and entered judgment against her for 15 counts of failure to prepare and maintain records with intent to defraud or mislead in violation of 21 U.S.C. 331(e), 333(a)(2), and 18 U.S.C. 2.

FDA's finding that debarment is appropriate is based on the felony convictions referenced herein for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act. The factual basis for those convictions is as follows: Dr. Palazzo was a licensed medical doctor with offices located in New Orleans, Louisiana. SmithKline Beecham, Corporation, d.b.a. GlaxoSmithKline (SKB) was a pharmaceutical company engaged in developing, testing, and marketing pharmaceutical products including Paroxetine, also known as "Paxil." Under the FD&C Act and its implementing regulations, SKB had to apply to FDA for approval to market Paxil. SKB was required to demonstrate, through clinical investigations in which Paxil was given to human subjects, the safety and effectiveness of the drug in order to receive approval from FDA.

SKB hired Dr. Palazzo to be a clinical investigator for the Paxil study. As a participating investigator, Dr. Palazzo signed, on multiple occasions, an FDA Form 1572 committing to conduct the study in accordance with the study protocol, to personally conduct or supervise the investigation, and to comply with FDA regulations. Dr. Palazzo agreed to conduct the study in strict compliance with the criteria set forth in the study protocol, to personally review all Case Report Forms, and, in return, SKB agreed to pay for each subject who completed the study.

FDA regulations require that a clinical investigator on a drug study prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each study subject and provide that information to the drug sponsor. From on or about October 23, 2000, through May 24, 2001, Dr. Palazzo, with intent to defraud and mislead, failed to prepare and maintain records required under 21 U.S.C. 355(i) and 21 CFR 312.62(b), all in violation of 21 U.S.C. 331(e), 333(a)(2), and 18 U.S.C. 2.

As a result of her convictions, on January 11, 2011, FDA sent Dr. Palazzo a notice by certified mail proposing to permanently debar her 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)(A) and (B) of the FD&C Act, that Dr. Palazzo was convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act. The proposal also offered Dr. Palazzo an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Dr. Palazzo failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(a)(2)(A) and(B) of the FD&C Act, under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Maria Carmen Palazzo has been convicted of felonies under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product and otherwise relating to the regulation of any drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Palazzo 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