

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 4, 2011.

A. Federal Reserve Bank of Atlanta (Clifford Stanford, Vice President) 1000 Peachtree Street, NE., Atlanta, Georgia 30309:

1. *Teche Holding Company*, New Iberia, Louisiana; to become a bank holding company by acquiring 100 percent of the outstanding shares of *Teche Federal Bank*, New Iberia, Louisiana.

Board of Governors of the Federal Reserve System, March 7, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-11-11BI]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

FoodNet Non-O157 Shiga toxin-Producing *E. coli* Study: Assessment of Risk Factors for Laboratory-Confirmed Infections and Characterization of Illnesses by Microbiological Characteristics—New—National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Each year many Shiga toxin-producing *E. coli* (STEC) infections occur in the United States, ranging in severity from mild diarrhea, to hemorrhagic colitis and in some cases, life-threatening hemolytic uremic syndrome (HUS). HUS occurs most frequently following infection with serogroup O157; 6% of patients with this type of STEC infection develop HUS, with highest occurrence in children aged < 5 years. HUS has a fatality rate of approximately 5%; up to 25% of HUS survivors are left with chronic kidney damage. STEC are broadly categorized into two groups by their O antigens, STEC O157 and non-O157 STEC. The serogroup O157 is most frequently isolated and most strongly associated with HUS. Risk

factors for STEC O157 infections in the United States and internationally have been intensely studied. Non-O157 STEC are a diverse group that includes all Shiga toxin-producing *E. coli* of serogroups other than O157. Over 50 STEC serogroups are known to have caused human illness. Numerous non-O157 outbreaks have been reported from throughout the world and clinical outcomes in some patients can be as severe as those seen with STEC O157 infections, however, little is known about the specific risk factors for infections due to non-O157 STEC serogroups. More comprehensive understanding of risk factors for sporadic non-O157 STEC infections is needed to inform prevention and control efforts. The FoodNet case-control study will be the first multistate investigation of non-outbreak-associated non-O157 STEC infections in the United States. It will investigate risk factors for non-O157 STEC infections, both as a group and individually for the most common non-O157 STEC serogroups. In addition, the study will characterize the major known virulence factors of non-O157 STEC to assess how risk factors and clinical features vary by virulence factor profiles. As the largest, most comprehensive, and most powerful study of its kind, it could make an important contribution towards better understanding of non-O157 STEC infections and to providing science-based recommendations for interventions to prevent these infections.

Persons with non-O157 STEC infections who are identified as part of routine public health surveillance and randomly selected healthy persons in the patients' communities (to serve as controls) will be contacted and offered enrollment into this study. Participation is completely voluntary and there is no cost for enrollment. The total estimated annualized burden is 268 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Patients	161	1	25/60
Controls	483	1	25/60

Catina Conner,

Acting Reports Clearance Officer, Centers for Disease Control and Prevent.

[FR Doc. 2011-5460 Filed 3-9-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0479]

Mark E. Van Wormer: 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 debaring Mark E. Van Wormer, MD, 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. Van Wormer was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Van Wormer was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. In a January 1, 2011, letter to FDA, Dr. Van Wormer notified FDA that he did not plan to seek a hearing and therefore has waived his right to a hearing concerning this action.

DATES: This order is effective March 10, 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)(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 otherwise relating to the regulation of any drug product under the FD&C Act.

On December 13, 2007, the U.S. District Court, District of New Mexico, entered judgment against Dr. Van

Wormer for felony misbranding a drug while held for sale in violation of 21 U.S.C. 333(a)(2), 331(k) and 352(i)(3).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the regulation of a drug product. The factual basis for the conviction is as follows: Dr. Van Wormer is a physician licensed by the New Mexico State Board of Medicine, and he owned and operated the Union County Medical Center, also known as the Union County Medical, Diagnostic Imaging and Laser Surgery Center, PC, and the Physicians GreatSkin® Clinic.

From on or about January 13, 2004, through on or about November 9, 2004, Dr. Van Wormer advertised the use of Allergan's approved BOTOX for use in treatment of forehead wrinkles. However, during that time he knowingly used TRI-toxin, an unapproved botulinum toxin type A product, that he purchased from Toxin Research International, Inc. (TRI), a company in Tucson, AZ.

Dr. Van Wormer purchased approximately 20 vials of the TRI-toxin, which he injected into his patients. He did not inform his patients that they were being injected with an unapproved substance, and patients were charged as if they were receiving the approved drug product. Dr. Van Wormer injected approximately 120 patients with the unapproved TRI-toxin.

As a result of his convictions, on December 17, 2010, FDA sent Dr. Van Wormer 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 Dr. Van Wormer was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Dr. Van Wormer 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. Dr. Van Wormer submitted a letter dated January 1, 2011, acknowledging receipt of the proposal to debar and noting that he did not plan to seek a further hearing regarding the matter and thereby has waived his opportunity for a hearing and 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 Mark E. Van Wormer has been convicted of a felony 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 and based on his notification of acquiescence, Dr. Van Wormer 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 section 306(c)(1)(B), (c)(2)(A)(ii), (c)(2)(B) of the FD&C Act and section 201(dd) of the FD&C Act (21 U.S.C.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 Dr. Van Wormer, in any capacity during Dr. Van Wormer's 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 Dr. Van Wormer 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). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Van Wormer during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Van Wormer for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2010-N-0479 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 16, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

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